

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**DEFENDANTS’ MOTION TO EXCLUDE  
CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter “Defendants”) move to exclude certain general opinions of one of Plaintiffs’ experts, Daniel Elliott, M.D., that are improper and/or are beyond his expertise as a pelvic surgeon and urogynecologist. Specifically, Defendants request that the Court preclude Dr. Elliott from: (1) Testifying that non-synthetic mesh procedures are a safer alternative for the surgical treatment of stress urinary incontinence and pelvic organ prolapse, because such procedures are not alternative designs and are irrelevant to a design-defect claim and because such opinions are unreliable; (2) Offering design opinions, because he is not qualified to do so and his opinions are unreliable and not offered within a reasonable degree of medical certainty; (3) Criticizing the cut of TVT mesh, because his opinions are unreliable and conflicting; (4) Speculating about the duties of a medical device manufacturer, because he is not qualified to do so and such opinions are irrelevant and inadmissible to the extent that they contain legal conclusions; (5) Testifying about alleged mesh degradation, shrinkage, contraction, and other biomaterials opinions, because such opinions are unreliable, irrelevant, and/or otherwise improper; (6) Offering opinions about regulatory

compliance and marketing, because he is not qualified to do so and such opinions are prejudicial, inflammatory, improper, speculative, and irrelevant; and (7) Offering opinions beyond Dr. Elliott's expertise and/or that are otherwise improper, because he is not qualified to do so and such opinions are inadmissible, unreliable, and/or draw legal conclusions.

As grounds for this motion, Defendants submit that Dr. Elliott cannot provide reliable, trustworthy and/or admissible testimony about these topics under the standard set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). In support of this motion, Defendants incorporate by reference their accompanying memorandum of law and rely on the following Exhibits:

1. List of cases in which Dr. Elliott has been designated by Plaintiff(s) as a general expert, Exhibit A;
2. Dr. Elliott's curriculum vitae, Exhibit B;
3. Dr. Elliott's TVT General Expert Report, Exhibit C;
4. Dr. Elliott's TVT-O General Expert Report, Exhibit D;
5. Dr. Elliott's TVT-Secur General Expert Report, Exhibit E;
6. Dr. Elliott's Prolift General Expert Report, Exhibit F;
7. Transcript of Dr. Elliott's September 26, 2015 Deposition, Exhibit G;
8. Heinonen, *et. al.*, *Tension-free vaginal tape procedure without preoperative urodynamic examination: Long-term outcome*, Int'l. Journal of Urology (2012), Exhibit H;
9. American Urological Association Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update, Exhibit I;
10. American Journal of Obstetrics & Gynecology SGS Study (2014), Exhibit J;
11. *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Order (S.D. W. Va. Nov. 20, 2014), Exhibit K;
12. Transcript of Dr. Elliott's November 15, 2015 Deposition, Exhibit L;

13. Transcript of Dr. Elliott's November 16, 2015 Deposition, Exhibit M;
14. Garcia-Urena, *Differences in polypropylene shrinkage depending on mesh position in an experimental study*, The American Journal of Surgery (2007), Exhibit N;
15. Mamy, et. al., *Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection*, The International Urogynecological Association (2010), Exhibit O;
16. Feiner and Maher, *Vaginal Mesh Contraction*, American College of Obstetricians and Gynecologists (2010), Exhibit P;
17. Sunoco Material Safety Data Sheet, Exhibit Q;
18. Dr. Elliott's TVT Report reliance list, Exhibit R;
19. R. Langer, et al., *Long-Term (10-15 years) Follow-Up after Burch Colposuspension for Urinary Stress Incontinence*, International Urogynecology Journal (2001), Exhibit S;
20. Mayo Clinic Urinary Incontinence Webpage, Exhibit T;
21. Ford, et al., *Mid-urethral sling operations for stress urinary incontinence*, Cochrane Collaboration (2015), Exhibit U; and
22. Wang, et al, *A histologic and immunohistochemical analysis of defective vaginal healing after continence taping procedures: A prospective case-controlled pilot study*, American Journal of Obstetrics and Gynecology (2004), Exhibit V.

WHEREFORE, FOR THESE REASONS and as more fully set forth in Ethicon's supporting memorandum of law, Ethicon respectfully requests that this Court enter an order granting Ethicon's Motion to Exclude the Testimony of Dr. Daniel Elliott, M.D.

Respectfully Submitted,

/s/ Christy D. Jones

Christy D. Jones  
Butler Snow LLP  
1020 Highland Colony Parkway  
Suite 1400 (39157)  
P.O. Box 6010  
Ridgeland, MS 39158-6010

(601) 985-4523  
[Christy.jones@butlersnow.com](mailto:Christy.jones@butlersnow.com)

/s/ David B. Thomas  
David B. Thomas (W. Va. Bar #3731)  
Thomas Combs & Spann PLLC  
300 Summers Street  
Suite 1380 (25301)  
P.O. Box 3824  
Charleston, WV 25338  
(304) 414-1807  
[dthomas@tcspllc.com](mailto:dthomas@tcspllc.com)

COUNSEL FOR DEFENDANTS  
ETHICON, INC. AND  
JOHNSON & JOHNSON



**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<hr/> <b>THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

Christy D. Jones  
Butler Snow LLP  
1020 Highland Colony Parkway  
Suite 1400 (39157)  
P.O. Box 6010  
Ridgeland, MS 39158-6010  
(601) 985-4523  
christy.jones@butlersnow.com

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
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**EXHIBIT A TO MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF  
DANIEL ELLIOTT, M.D.**

**ALL CASES PERTINENT TO MOTION**

1. *Joan Adams v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01203 (Prolift);
2. *Donna Amsden v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00960 (Prolift);
3. *Dina Sanders Bennett v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00497 (Prolift & TVT-Secur);
4. *Sharon Boggs, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00368 (TVT-O & Prolift);
5. *Myra Byrd, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00748 (TVT-O);
6. *Sharon Carpenter, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00554 (Prolift);
7. *Melissa Clayton, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00489 (Prolift);
8. *Carey Beth Cole, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00483 (Prolift);
9. *Fran Denise Collins v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00931 (TVT-O);
10. *Mary F. Cone v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00261 (TVT-O);
11. *Amanda Deleon, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00358 (Prolift);
12. *Dina Destefano-Raston, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01299 (TVT-O);
13. *Carol Jean Dimock v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00401 (Prolift & TVT-O);

14. *Karen Forester, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00486 (TVT-O);
15. *Betty Funderburke v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00957 (Prolift & TVT);
16. *Teresa Georgilakis, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00829 (TVT-O);
17. *Pamela Gray-Wheeler v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00455 (Prolift & TVT-Secur);
18. *Susan Guinn v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01121 (TVT-O);
19. *Rocio Herrera-Nevarez v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01294 (TVT-O);
20. *Barbara Hill, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00806 (Prolift);
21. *Joyce Justus v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00956 (Prolift);
22. *Barbara Kaiser v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00887 (Prolift);
23. *Diane Kropf, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01202 (Prolift & TVT-O);
24. *Heather Long v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-001275 (TVT);
25. *Donna Loustaunau, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00666 (Prolift);
26. *Deborah Lozano, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00347 (Prolift && TVT-O);
27. *Dee McBrayer, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00779 (Prolift Posterior);
28. *Tina Morrow, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00378 (Prolift Total & TVT-O);
29. *Cynthia Nix v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01278 (Prolift Anterior, Prolift Total & TVT-O);
30. *Mary Jane Olson, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00470 (Prolift Total & TVT-O);
31. *Noemi Padilla, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00567 (Prolift +M Posterior);
32. *Patti Ann Phelps, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01171 (TVT);

33. *Rebecca Pratt v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01273 (TVT);
34. *Maria Eugenia Quijano v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00799 (TVT);
35. *Penny Rhynehart v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01119 (Prolift Total & TVT-O);
36. *Debra Schnering, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01071 (TVT);
37. *Donna Shepherd v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00967 (TVT-Secur);
38. *Teri Key Shively v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00379 (Prolift Posterior & TVT-O);
39. *Cherise Springer, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00997 (TVT-O);
40. *Maria C. Stone, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00652 (Prolift Posterior);
41. *Charlene Logan Taylor v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00376 (Prolift Posterior & TVT-O);
42. *Kimberly Thomas v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00499 (Prosima Anterior & TVT-O);
43. *Mary Thurston, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00505 (TVT);
44. *Judy G. Williams v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00657 (Prolift Posterior & TVT-O);
45. *Nancy Williams v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00511 (Prolift Total & TVT-O);
46. *Blynn Wilson v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00921 (Prolift Total);
47. *Christine Wiltgen, et al. v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-01216 (TVT);  
and
48. *Sandra Wolfe v. Ethicon, Inc., et al.*, Civil Action No. 2:12-cv-00335 (Prolift Total & TVT-O).

\* Defendants reserve the right to supplement this list should any plaintiff designate Dr. Elliott as general causation expert in MDL Wave 1.

## EXHIBIT A

## Curriculum Vitae and Bibliography

**Daniel S Elliott, MD**

### Present Academic Rank and Position

<b>Consultant</b> - Department of Urology, Mayo Clinic, Rochester, Minnesota	07/2003 - Present
<b>Associate Professor of Urology</b> - Mayo Clinic College of Medicine	01/2013 - Present

### Education

Biola University - BS, Biological Science	1988
School of Medicine, Loma Linda University - MD	1993
Mayo School of Graduate Medical Education, Mayo Clinic College of Medicine - Internship, General Surgery	1993 - 1994
Mayo School of Graduate Medical Education, Mayo Clinic College of Medicine - Resident, Urologic Surgery	1994 - 1999
Baylor College of Medicine - Fellow, Neurourology, Urodynamics and Voiding Dysfunction	1999 - 2000

### Certification

#### Board Certifications

##### American Board of Urology

Urology	2002 - 2012
Urology/Female Pelvic Medicine and Reconstructive Surgery	2013 - Present

### Honors and Awards

<b>AUA Resident Award</b> - John D. Silbar North Central Section	10/1998
<b>Urology Grant Recipient</b> - Pfizer Scholars	01/1999
<b>DeWeerd Travel Award Recipient</b> - Awarding Organization	06/1999
<b>Annual Audio-Visual Award - AUA</b> - American Urological Association, Washington, District of Columbia	05/2011
<b>Best Reviewer in 2011 Award - Urodynamics/Incontinence/Female Urology/Neurourology</b> - The Journal of Urology	05/2012
<b>Annual Audio-Visual Award - AUA</b> - American Urological Association, San Diego, California	05/2013
<b>Best Reviewer in 2012 Award - Urodynamics/Incontinence/Female Urology/Neurourology</b> - The Journal of Urology	05/2013
<b>Kelalis Resident Essay Competition</b> - Minnesota Urological Society, Lakeland, Minnesota	02/2015
<b>The North Central Traveling Fellowship Award</b> - North Central Section American Urological Association	11/2015

### Previous Professional Positions and Major Appointments

<b>Senior Associate Consultant</b> - Department of Urology, Mayo Clinic, Rochester, Minnesota	07/2000 - 06/2003
<b>Assistant Professor of Urology</b> - Mayo Clinic College of Medicine	04/2002 - 12/2012

### Professional and Community Memberships, Societies, and Services

**Professional Memberships and Services**

American Association of Clinical Urologists	
Member	1998 - 2005
American Medical Association	
Member	1991 - 2001
American Urological Association	
Member	2000 - Present
European Association of Urology	
International Member	03/2013 - Present
Section of Female and Functional Urology	
International Member	04/2013 - Present
Section of Genitourinary Reconstructive Surgeons	
International Member	03/2013 - Present
Committee Member	04/2014 - Present
International Continence Society	
Member	2001 - Present
International Pelvic Pain Society	
Member	05/2014 - Present
International Urogynecologic Association	
Member	05/2013 - Present
International Urogynecologic Society	
Member	2003 - Present
Minimally Invasive Robotic Association	
Member	2005 - Present
Minnesota Medical Association	
Member	2002 - Present
Zumbro Valley Medical Society	
Member	2002 - Present
Minnesota Urological Society	
Member	2006 - Present
Olmsted County Medical Association	
Member	2002 - Present
Society for Urodynamics & Female Urology	
Member	2002 - Present
Education Committee	
Committee Member	08/2014 - Present
Society of Laparoendoscopic Surgeons	
Member	2005 - Present
Society of Urologic Prosthetic Surgeons	
Member	2005 - Present

**Journal Responsibilities**

**Journal Editorial Responsibilities**

Journal of Gynecology and Obstetrics
Editorial Board Member

Journal of Robotic Surgery  
Consulting Editor

#### **Journal Other Responsibilities**

Archives of Gynecology and Obstetrics  
Reviewer  
Canadian Urological Association Journal  
Reviewer  
Cleveland Clinic Journal of Medicine  
Reviewer  
Contemporary Clinical Trials  
Reviewer  
European Journal of Obstetrics & Gynecology and Reproductive Biology  
Reviewer  
European Urology  
Reviewer  
International Urogynecology Journal  
Reviewer  
Journal of Endourology  
Reviewer  
Journal of Investigative Urology  
Reviewer  
Mayo Clinic Health Letter  
Reviewer  
Mayo Clinic Proceedings  
Reviewer  
Nature Clinical Practice Urology  
Reviewer  
Neurourology and Urodynamics  
Reviewer  
Obstetrics & Gynecology International Journal  
Reviewer  
The Journal of Urology  
Reviewer  
Urologia Internationalis  
Reviewer

#### **Educational Activities**

##### **Teaching Intramural**

Prostate Pathology  
Mayo Medical School  
Rochester, Minnesota

03/2005

#### **Institutional/Departmental Administrative Responsibilities, Committee Memberships, and Other Activities**



## Mayo Clinic

Mayo Clinic Formulary Committee

Committee Member

2000 - 2003

## Mayo Clinic in Rochester

Department of Urology

Clinical Competency Committee

Chair

01/01/2015 - Present

Committee Member

10/15/2013 - Present

Clinical Practice Committee

Committee Member

2000 - 2004

Education Committee

Committee Member

02/11/2003 -  
11/11/2008

Committee Member

10/15/2013 - Present

## Presentations Extramural

### National or International

#### Invited

Robotic Urogynecologic Surgery

03/2008

3rd Annual World Robotic Urology Symposium

Orlando, Florida

Robotic Sacrocolpopexy

01/2009

2009 International Robotic Urology Symposium (IRUS), Henry Ford Health System

Las Vegas, Nevada

Current Status Robotic GYN Surgery

01/2010

2010 International Robotic Urology Symposium (IRUS), Henry Ford Health System

Las Vegas, Nevada

Robotic Sacrocolpopexy

09/2010

28th World Congress on Endourology and SWL

Chicago, Illinois

Female Urology

09/2010

28th World Congress on Endourology and SWL

Chicago, Illinois

Optimizing Quality of Life With Regard to Urologic Function After Sacrectomy

01/2013

The 4th Annual Sacral Tumor Study Group Conference, Massachusetts General  
Hospital

Boston, Massachusetts

A Comparison of Artificial Urinary Sphincter Device Outcomes Among Patients With  
and Without Diabetes

02/2015

Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction  
(SUFU)

Scottsdale, Arizona

A Prospective Evaluation of Complications After Artificial Urinary Sphincter Placement and Their Impact on Device Survival 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Autologous Transobturator Urethral Sling Placement for Female Stress Urinary Incontinence 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Effects of Radiation Therapy on Device Survival Among Individuals with Artificial Urinary Sphincters 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Holmium Laser Excision of Genitourinary Mesh Exposure Following Anti-Incontinence Surgery: Minimum 6 Month Follow-up 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Outcomes for Artificial Urinary Sphincter Placement After Prior Male Urethral Sling Failure 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

The Effect of BMI on Primary Artificial Urinary Sphincter Outcomes Among Males with Stress Urinary Incontinence 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Treatment of Bladder and Urethral Mesh Erosion: Remove and Reconstruct 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Urethral Management During Artificial Urinary Sphincter Explantation for Erosion 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Male Urinary Incontinence Management 05/2015  
 Association Fran&#231;aise d&#8217;Urologie (AFU) / American Urological Association (AUA)  
 New Orleans, Louisiana

Negative Impact of Prior Sling on AUS Device Survival 11/2015  
 North Central Section of the American Urological Association (AUA)  
 United States of America

**Oral**

Long Term Follow-Up of Endoscopically Treated Upper Tract Transitional Cell Carcinoma 04/1995  
 American Urological Association Annual Meeting  
 Las Vegas, Nevada

Long Term Analysis of 323 AMS 800 Artificial Urinary Sphincters 05/1996  
 Urodynamics Subsection Meeting, American Urological Association  
 Orlando, Florida

Transabdominal Enzymatic Ablation of the Prostate in the Canine Model: Evaluation for Use for the Treatment of Outflow Obstruction Due to Benign Prostatic Hyperplasia 05/1996  
 Urodynamics Subsection Meeting, American Urological Association  
 Orlando, Florida

Analysis of Functional Durability of AMS 800 Artificial Urinary Sphincter: The Mayo Clinic Results 04/1997  
 American Urological Association Annual Meeting  
 New Orleans, Louisiana

Long Term Follow-Up Primary Realignment of Urethral Disruption Following Pelvic Fracture 04/1997  
 American Urological Association Annual Meeting  
 New Orleans, Louisiana

Does Reoperation on an Artificial Urinary Sphincter Increase the Likelihood for Further Reoperations for Mechanical or Nonmechanical Failure? 06/1998  
 American Urological Association Annual Meeting  
 San Diego, California

Is Nephroureterectomy Necessary in All Cases of Upper Tract Transitional Cell Carcinoma? Long Term Results of Conservative Endourology Management of Upper Tract Transitional Cell Carcinoma in Individuals with Normal Contralateral Kidneys 05/1999  
 American Urological Association Annual Meeting  
 Dallas, Texas

Durability of Cadaveric Pubovaginal Sling 06/2001  
 American Urological Association Annual Meeting  
 Anaheim, California

Does the Addition of Antibiotic Prophylaxis to CIC Alter the Incidence of UTI? 06/2002  
 American Urological Association Annual Meeting

Orlando, Florida

Surgical Approach for Placement of SPARC Suburethral Sling 10/2002  
North Central Section, American Urological Association  
Chicago, Illinois

SPARC suburethral sling: technique and results (Video Presentation) 11/2002  
Western Section, American Urological Association  
Kauai, Hawaii

Robotic laparoscopic sacrocolpopexy: new surgical technique for the treatment of 04/2003  
vaginal vault prolapse (Video Presentation)  
American Urological Association  
Chicago, Illinois

08/2004  
Colloquium-ICS/IUGA 2004  
Paris, France

Robotic-Assisted Laparoscopic Management of Vaginal Vault Prolapse 12/2005  
Minimally Invasive Robotics Association  
Innsbruck, Austria

Advancement in Salvage Procedure Following Failed Artificial Urinary Sphincter: 05/2006  
Tandem Transcortical Artificial Urinary Sphincter Cuff Technique (Video  
Presentation)  
American Urological Association  
Atlanta, Georgia

Tandem Transcortical Artificial Urinary Sphincter Cuff Salvage Technique 10/2006  
Following Previous Cuff Erosion and Infection: Surgical Description and Outcome  
Western Section, American Urological Association  
Maui, Hawaii

Assessment of Durability of Robotic Sacrocolpopexy for the Treatment of Vaginal 01/2007  
Vault Prolapse  
Minimally Invasive Robotics Association  
New York, New York

Minimally Invasive Advances: Stress Incontinence 02/2007  
Mayo Clinic Rochester, Department of Urology  
Kohala Coast, Hawaii

Treatment Options for the Failed Sling 02/2007  
Mayo Clinic Rochester, Department of Urology  
Kohala Coast, Hawaii

05/2007  
American Urological Association Annual Meeting

Anaheim, California

Robotics use in Gynecology: the Mayo Clinic experience 06/2007  
 Robotic Surgery: Facts or Fiction?  
 Milano, Italy

Indication and Management of Artificial Urinary Sphincter 10/2007  
 7th Osijek Urological Days  
 Osijek, Croatia

Robotics Use in Gyenocology 10/2007  
 7th Osijek Urological Days  
 Osijek, Croatia

Robotic Urogynecologic Surgery 03/2008  
 3rd Annual World Robotic Urlogy Symposium  
 Orlando, Florida

Latest Advances and Treatment of Complications in Minimally Invasive Treatments 05/2008  
 for Stress Incontinence  
 American Urological Association (AUA)  
 Orlando, Florida

Severe, recurrent bladder neck contracture after prostatectomy: Salvage with 05/2008  
 urethral wall stent(Video and Poster Presentation)  
 American Urological Association (AUA)  
 Orlando, Florida

Surgical Advances of Stress Urinary Incontinence 05/2008  
 Indian American Urological Association (IAUA)  
 Orlando, Florida

Robotic Sacrocolpopexy 01/2009  
 International Robotic Urology Symposium, Henry Ford Health System  
 Las Vegas, Nevada

Management of Complications Following Anti-Incontinence Procedures 02/2009  
 Mayo Clinic, Department of Urology, Rochester Meeting  
 Kona, Hawaii

Minimally Invasive Advances: Stress Incontinence 02/2009  
 Mayo Clinic, Department of Urology, Rochester Meeting  
 Kona, Hawaii

Overactive Bladder: Current Concepts of Management 02/2009  
 Mayo Clinic, Department of Urology, Rochester Meeting  
 Kona, Hawaii

American Urological Association (AUA) Chicago, Illinois	04/2009
Robotic repair for vaginal prolapse has significant benefits North Central Section of the AUA - 83rd Annual Meeting Scottsdale, Arizona	11/2009
Current Status Robotic GYN Surgery International Robotic Urology Symposium, Henry Ford Health System Las Vegas, Nevada	01/2010
Robotics for Female Pelvic Reconstruction: Who, When and What? American Urological Association (AUA) San Francisco, California	05/2010
Results of Urethral Wrap As Salvage Treatment Option Following Multiple Failed Artificial Urinary Sphincters North Central Section of the AUA Chicago, Illinois	09/2010
Small intestinal submucosa urethral wrap as a salvage treatment option following multiple failed artificial urinary sphincters Audio-Visual American Urological Association (AUA) Washington, District of Columbia	05/2011
Long-Term Results of Small Intestinal Submucosa at Artificial Urinary Sphincter Placement for Management of Persistent / Recurrent Incontinence Following Multiple Sphincter Failures and Erosions North Central Section of the AUA Rancho Mirage, California	10/2011
OAB Current Concepts and Management Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Transvaginal Mesh Kits Complications and Alternatives Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Treatment and Evaluation of the Complicated Artificial Urinary Sphincter Patient Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Vaginal Mesh for POP: what's the data show? American Urological Association (AUA) Atlanta, Georgia	05/2012

How do different centres perform Robot-assisted-Sacrocolpopexy? 4th Annual Society of European Robotic Gynecological Surgery (SERGS) Marseille, France	06/2012
Comparative Surgical Complications of the Robotic Sacrocolpopexy for Pelvic Organ Prolapse vs. Traditional Transabdominal Sacrocolpopexy European Robotic Urology Symposium (ERUS) London, United Kingdom	09/2012
Infection of Antibiotic-Coated Artificial Urinary Sphincters North Central Section of the AUA Chicago, Illinois	10/2012
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Impact of Patient Obesity on Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Robotic Transvesical Rectourethral Fistula Repair Following a Robotic Radical Prostatectomy (Video Presentation) Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
The Impact of Prior Radiotherapy on Outcomes Following Surgical Repair of a Rectourethral Fistula in Men with Prostate Cancer Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas American Urological Association (AUA) San Diego, California	05/2013
Impact of Patient Obesity on Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse American Urological Association (AUA) San Diego, California	05/2013
Long Term Risk for Repeat Anti-Incontinence Surgery following Urethrolysis: A Review of 100 Patients American Urological Association (AUA) San Diego, California	05/2013

Long-Term Outcomes of Patients Undergoing the Standard Versus Modified (5 Points of Fixation, 1 Point of Plication) Technique for Virtue Male Sling Placement (Video Presentation) 05/2013  
 American Urological Association (AUA)  
 San Diego, California

Robotic Transvesical Rectourethral Fistula Repair Following a Robotic Radical Prostatectomy (Video Presentation) 05/2013  
 American Urological Association (AUA)  
 San Diego, California

The Impact of InhibiZone on Artificial Urinary Sphincter Infection Rate 05/2013  
 American Urological Association (AUA)  
 San Diego, California

Impact of patient obesity on robotic sacrocolpopexy for the treatment of vaginal vault prolapse 06/2013  
 3rd International Meeting &quot;Challenges in Endourology & Functional Urology&quot;  
 Paris, France

Long-Term Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Device Explantation for Erosion and/or Infection 09/2013  
 South Central Section of the AUA  
 Chicago, Illinois

Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas 10/2013  
 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU  
 T&#252;bingen, Germany

Impact of patient obesity on robotic sacrocolpopexy for the treatment of vaginal vault prolapse 10/2013  
 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU  
 T&#252;bingen, Germany

Long Term Risk for Need to Repeat Anti-Incontinence Surgery Following Urethrolisis: A Review of 144 Patients 10/2013  
 North Central Section of the AUA  
 Naples, Florida

Long-term impact of artificial urinary sphincter reimplantation following prior device explantation for erosion and/or infection 10/2013  
 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU  
 T&#252;bingen, Germany

Long-Term Outcomes for Artificial Urinary Sphincter Reimplantation after Explanation for Erosion or Infection 10/2013  
 North Central Section of the AUA  
 Naples, Florida



Simultaneous Cuff-Only Artificial Urinary Sphincter at Augmentation Cystoplasty in Children and Young Adults North Central Section of the AUA Naples, Florida	10/2013
Long-Term Device Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Explantation for Erosion or Infection Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction Miami, Florida	02/2014
Risk Factors for Intraoperative Conversion During Robotic Sacrocolpopexy Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction Miami, Florida	02/2014
Results of artificial urinary sphincter reimplantation following previous erosion and/or infection 29th Annual Congress of the European Association of Urology Stockholm, Sweden	04/2014
Autologous Transobturator Mid-Urethral Sling Placement: A Novel Outpatient Procedure for Female Stress Urinary Incontinence (Video Presentation) American Urological Association (AUA) Orlando, Florida	05/2014
Surgical Management of Female Benign Urethral Stricture Disease: A Ten Year Experience American Urological Association (AUA) Orlando, Florida	05/2014
Autologous Transobturator Mid-Urethral Sling Placement for Female Stress Urinary Incontinence (Video Presentation) North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014
Urethral Management at the Time of Artificial Urinary Sphincter Erosion, Is Urethral Catheterization Alone Enough? North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014
Holmium Laser Excision of Genitourinary Mesh Exposure Following Anti-Incontinence Surgery: Minimum 6 Month Follow-up American Urological Association (AUA) New Orleans, Louisiana	05/2015
A Comparison of Artificial Urinary Sphincter Device Outcomes Among Patients with and Without Diabetes North Central Section of the American Urological Association (AUA) Amelia Island, Florida	11/2015

Autologous Transobturator Urethral Sling Placement for Female Stress Urinary Incontinence 11/2015  
 North Central Section of the American Urological Association (AUA)  
 Amelia Island, Florida

Effects of Radiation Therapy on Device Survival Among Individuals with Artificial Urinary Sphincters 11/2015  
 North Central Section of the American Urological Association (AUA)  
 Amelia Island, Florida

Infection/Erosion Rates for Artificial Urinary Sphincter Revision After Mechanical Device Failure or Urethral Atrophy 11/2015  
 North Central Section of the American Urological Association (AUA)  
 Amelia Island, Florida

Long Term Continence Outcomes and Retreatment Rates Following Artificial Urinary Sphincter Placement: An Analysis of 1082 Cases at Mayo Clinic 11/2015  
 North Central Section of the American Urological Association (AUA)  
 Amelia Island, Florida

The Prospective Impact of Body Mass Index on Primary Artificial Urinary Sphincter Outcomes Among Males with Stress Urinary Incontinence 11/2015  
 North Central Section of the American Urological Association (AUA)  
 Amelia Island, Florida

#### Poster

Robot-Assisted Laparoscopic Sacrocolpopexy for Treatment of High Grade Vaginal Vault Prolapse: Surgical Technique and Initial Experience 09/2007  
 29th Congress of the Societe Internationale d'Urologie  
 Paris, France

Robot Sacrocolpopexy: A Review of the Learning Curve in Fifty Cases 01/2011  
 4th World Congress on Controversies in Urology (CURy)  
 Paris, France

Impact of Radiotherapy on Surgical Repair and Outcomes in Patients with Rectourethral Fistula. 06/2012  
 67th Annual Meeting of the Canadian Urological Association  
 Alberta, Canada

Outcomes and Predictors of Reoperation After Sling Release Surgery 05/2014  
 American Urological Association (AUA)  
 Orlando, Florida

Term Device Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Explantation for Erosion or Infection 05/2014  
 American Urological Association (AUA)  
 Orlando, Florida

Factors Associated with Intraoperative Conversion During Robotic Sacrocolpopexy 09/2014  
 North Central Section of the American Urological Association (AUA)  
 Chicago, Illinois

A Prospective Evaluation of Complications After Artificial Urinary Sphincter 05/2015  
 Placement and Their Impact on Device Survival  
 American Urological Association (AUA)  
 New Orleans, Louisiana

Artificial Urinary Sphincter Outcomes in Octogenarians 05/2015  
 American Urological Association (AUA)  
 New Orleans, Louisiana

Effects of Radiation Therapy on Device Survival Among Individuals with Artificial 05/2015  
 Urinary Sphincters  
 American Urological Association (AUA)  
 New Orleans, Louisiana

Perioperative Impact of Androgen Deprivation Therapy on Artificial Urinary 10/2015  
 Sphincter Placement  
 Western Section of the AUA  
 Indian Wells, California

The Protective Impact of Body Mass Index on Primary Artificial Urinary Sphincter 10/2015  
 Outcomes Among Males with Stress Urinary Incontinence  
 South Central Section of the American Urological Association (AUA)  
 Scottsdale, Arizona

## **Regional**

### **Invited**

Rectocele 10/2004  
 Office of Women's Health brown bag  
 Rochester, Minnesota

Incontinence and Other Urological Issues 08/2007  
 Radio Broadcast, Hosted by Dr. Thomas Shives  
 HealthLine - KROC Radio  
 Rochester, Minnesota

A Practical Approach to Treating Incontinence 10/2008  
 Clinical Reviews, Rochester Civic Center  
 Rochester, Minnesota

A Practical Approach to Treating Incontinence 11/2008  
 Clinical Reviews, Rochester Civic Center  
 Rochester, Minnesota

Incontinence and Other Urological Issues 03/2010  
 Radio Broadcast, Hosted by Dr. Thomas Shives  
 Medical Edge Weekend - KROC Radio  
 Rochester, Minnesota

Urinary Incontinence 03/2011  
 Radio Broadcast, Hosted by Dr. Thomas Shives  
 Medical Edge Weekend - KROC Radio  
 Rochester, Minnesota

Incontinence: Causes and Treatments 02/2013  
 Prostate Cancer Support Group  
 Rochester, Minnesota

Urinary Incontinence 05/2014  
 Radio Broadcast, Hosted by Dr. Thomas Shives  
 Medical Edge Weekend - KROC Radio  
 Rochester, Minnesota

Autologous Transobturator Urethral Sling Placement for Female Stress Urinary Incontinence 03/2015  
 Minnesota Urological Society (MUS) Spring Seminar  
 Minneapolis, Minnesota

Management of Concomitant SUI and Stricture Disease 08/2015  
 2015 Mayo Clinic Updates in Urology and Case Conference Program Schedule  
 Rochester, Minnesota

Managing the Mesh Mess - Diagnosing and Managing Mesh Complications and Non-Mesh Alternatives 08/2015  
 2015 Mayo Clinic Updates in Urology and Case Conference Program Schedule  
 Rochester, Minnesota

Surgical Tips to Optimize Outcomes of AUS Placement 08/2015  
 2015 Mayo Clinic Updates in Urology and Case Conference Program Schedule  
 Rochester, Minnesota

Incontinence 12/2015  
 Radio Broadcast, Hosted by Tracy McCray  
 Mayo Clinic Radio  
 Rochester, Minnesota

## Oral

Paratesticular Angiomyofibroblastoma 09/1995  
 North Central Section, American Urological Association  
 Minneapolis, Minnesota

Does the Degree of Preoperative Elevation PSA Exclude a Patient for 10/1996

Consideration for Radical Retropubic Prostatectomy?  
 North Central Section, American Urological Association  
 Tucson, Arizona

Does Reoperation of an Artificial Sphincter Place the Patient at an Increased Risk for Subsequent Reoperation 10/1998  
 North Central Section, American Urological Association  
 Amelia Island, Florida

Combined Stent and Artificial Urinary Sphincter for Management of Severe Recurrent Bladder Neck Contractures and Stress Incontinence after Prostatectomy: A Long-Term Evaluation. 10/2000  
 North Central Section, American Urological Association  
 Phoenix, Arizona

Does Nocturnal Deactivation of the Artificial Urinary Sphincter Lessen the Risk for Urethral Atrophy? 10/2000  
 North Central Section, American Urological Association  
 Phoenix, Arizona

Is Fascia Lata Allograft Material Trustworthy for Pubovaginal Sling Repair 10/2000  
 North Central Section, American Urological Association  
 Phoenix, Arizona

Robotics Surgery for Vaginal Prolapse 06/2007  
 Controversies in Women's Health Symposium 2007  
 Nisswa, Minnesota

# **Unclassified**

Artificial Urinary Sphincter Mechanical Failures: Is It Better To Replace The Entire Device Or Just The Malfunctioning Component? 02/2016  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

Effects Of Smoking Status On Device Survival Among Individuals Undergoing Artificial Urinary Sphincter Placement 02/2016  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

Long-Term Outcomes Following Artificial Urinary Sphincter Placement: An Analysis Of 1082 Cases At Mayo Clinic 02/2016  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

Long-Term Subjective And Functional Outcomes Of Primary And Secondary Artificial Urinary Sphincter Implantations Among Men With Stress Urinary Incontinence 02/2016  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

Predictors Of Poor Patient Satisfaction Following Primary AUS Placement Among Men With And Without A Prior History Of Radiation 02/2016  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

Temporal Pattern Of Artificial Urinary Sphincter (AUS) Cuff Erosions Indicating Differing Etiologies Of AUS Cuff Erosions 02/2016  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)

## Visiting Professorship

### Visiting Professorships

Minnesota Urological Society Pyelogram Conference 11/07/2014  
 The Artificial Urinary Sphincter: Proper Patient Selection, Implantation and Troubleshooting  
 Lakeland, Minnesota, United States of America

University of California Irvine 03/16/2015  
 AUS: Patient Selection and Complications Management  
 Irvine, California, United States of America

## Research Grants Awarded

### Completed Grants

#### Federal

Co-Investigator Selenium and Vitamin E Cancer Prevention Trial (SELECT). Funded by National Cancer Institute. (U10 CA 37429-SELECT) 01/2010 - 12/2010

#### Industry

Principal Investigator Are There Histological and Tensile Strength Variations in Autologous, Allograft and SIS Pubovaginal Slings Over Time Using the Rabbit Model. Funded by Mentor Corporation. (MENTOR #5, 1A4575) 10/2002 - 09/2003

Co-Investigator Single Looped Mechanical Urinary Sphincter: Determination of Required Urethral Constriction Forces to Provide Adequate Urinary Continence in the Canine Model. Funded by Dacomed, Inc.. (Dacomed #1) 10/1995 - 12/1995

Co-Investigator Clinical Investigation of the Safety and Performance of Timm Medical Technologies' Artificial Urinary Sphincter (TIMM-AUS). Funded by Timm Medical Technologies. (Timm # 1) 06/1999 - 02/2005

Co-Investigator A Randomized, Double-Blind, Parallel-Group Study to Investigate the Effects of a Single Oral Dose of L-753099 Compared to Placebo and Tolerodine on Urodynamic Parameters in Healthy Male Volunteers. Funded by Merck & Co., Inc.. (Merck 138) 07/1999 - 12/2003

Co-Investigator The Safety, Local Tolerability, Pharmacokinetics, and Risk Benefit of Oxybutynin Transvaginal Rings (TVR) in Women with a History of Overactive Bladder. Funded by Advanced Biologics. (BIOLOGICS #1) 01/2001 - 12/2003

Co-Investigator An Eight-Week, Double-Blind, Randomized, Parallel Group Design, Multicenter Study of FLOMAX Capsules, 0.4 mg Daily Vs. Placebo, in Female Patients w/ Lower Urinary Tract Symptoms (LUTS) w/ a Significant Component of Voiding Symptoms. Funded by Boehringer Ingelheim. (BOEHRINGER #34) 06/2001 - 07/2003

Co-Investigator Veritas Collagen Matrix Urological Sling Postmarketing Clinical Study Protocol. Funded by Bio-Vascular, Inc.. (BIOVASCULAR #1) 10/2001 - 09/2003

**Mayo Clinic**

Principal Investigator Transurethral Enzymatic Ablation of the Prostate (TEAP); Short-term Concentration Study. Funded by Department Discretionary Funds. (Immuno 2) 09/1995 - 12/2003

# Bibliography

## Peer-reviewed Articles

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4. **Elliott DS**, Barrett DM. The artificial urinary sphincter in the female: indications for use, surgical approach and results. Int Urogynecol J Pelvic Floor Dysfunct. 1998; 9(6):409-15. PMID:9891964
5. **Elliott DS**, Barrett DM. Mayo Clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. J Urol. 1998 Apr; 159(4):1206-8. PMID:9507835
6. Brown JA, **Elliott DS**, Barrett DM. Postprostatectomy urinary incontinence: a comparison of the cost of conservative versus surgical management. Urology. 1998 May; 51(5):715-20. PMID:9610584
7. **Elliott DS**, Barrett DM. The artificial genitourinary sphincter. Digital Urology Journal. 1998 Jul.
8. **Elliott DS**, Timm GW, Barrett DM. An implantable mechanical urinary sphincter: a new nonhydraulic design concept. Urology. 1998 Dec; 52(6):1151-4. PMID:9836575
9. **Elliott DS**, Boone TB. Urethral devices for managing stress urinary incontinence. Journal of Endourology. 2000 Feb; 14(1):79-83. PMID:10735576
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11. Frank I, **Elliott DS**, Barrett DM. Success of de novo reimplantation of the artificial genitourinary sphincter. J Urol. 2000 Jun; 163(6):1702-3. PMID:10799164
12. Petrou SP, **Elliott DS**, Barrett DM. Artificial urethral sphincter for incontinence. Urology. 2000 Sep 1; 56(3):353-9. PMID:10962293
13. **Elliott DS**, Boone TB. Is fascia lata allograft material trustworthy for pubovaginal sling repair? Urology. 2000 Nov 1; 56(5):772-6. PMID:11068297
14. **Elliott DS**, Boone TB. Recent advances in the management of the neurogenic bladder. Urology. 2000 Dec 4; 56(6 Suppl 1):76-81. PMID:11114567
15. **Elliott DS**, Boone TB. Combined stent and artificial urinary sphincter for management of severe recurrent bladder neck contracture and stress incontinence after prostatectomy: a long-term evaluation. J Urol. 2001 Feb; 165(2):413-5. PMID:11176385 DOI:10.1097/00005392-200102000-00014
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bladder dysfunction. J Urol. 2001 Mar; 165(3):903-4. PMID:11176503

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DOI:10.1016/j.juro.2006.10.052
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\* Indicates that the primary author was a mentee of this author.



**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>  <b>THIS DOCUMENT RELATES TO WAVE 1 CASES</b>	<b>Master File No. 2:12-MD-02327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
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**RULE 26 EXPERT REPORT OF DR. DANIEL ELLIOTT**

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## **I. Background and Qualifications**

I am an Associate Professor of Urology at Mayo Graduate School of Medicine in Rochester, Minnesota. I received an M.D. in 1993 from Loma Linda University School of Medicine in Loma Linda, California. Following graduation from medical school, I completed my surgical residency in Urology at the Mayo Graduate School of Medicine at the Mayo Clinic in 1999. I then completed a one-year advanced surgical fellowship at Baylor College of Medicine in Houston, Texas, in Neurourology, Urodynamics and Voiding Dysfunction. I then re-joined the faculty at the Mayo Clinic, where I have spent the last 15 years specializing in treating pelvic organ prolapse and urinary incontinence in women and urinary incontinence in men. I have published over 60 peer-reviewed articles and given over a hundred lectures, many of which relate to urinary incontinence and pelvic organ prolapse. A Mayo Clinic colleague and I were the first to perform robotic sacrocolpopexy surgery for the treatment of high-grade prolapse and to publish extensively on the subject. I am a frequent invited lecturer at medical and surgical conferences addressing pelvic organ prolapse and stress urinary incontinence and their evaluation, treatments, surgical options and management of complications. I have taken and passed the subspecialty credentialing process recently established by the combined boards of the American Board of Urology and American Board of Obstetrics and Gynecology in Female Pelvic Medicine and Reconstructive Surgery.

Attached, as Exhibit “A”, to this report is a copy of my current curriculum vitae, which includes an up-to-date list of my publications, presentations, awards, and other academic activities.

## **II. Basis of Opinion**

I have been asked to provide opinions regarding the subject of female stress urinary incontinence, its evaluation, treatments, surgical options and management of complications as well as to address the actions of Ethicon, Inc., Ethicon Women's Health and Urology, a Division of Ethicon, Inc., Gynecare and Johnson & Johnson (collectively referred to as Ethicon). The focus of my investigation for this report is on the Tension-Free Vaginal Tape-Retropubic ("TVT") and, specifically, the characteristics of the product that make it defective or, in other words, that make the risks to the patient outweigh the benefits to the patients. My opinions are based on my personal knowledge, experience, and my investigation in this case. All of my opinions, and the basis of those opinions, are true and correct to the best of my knowledge and belief, including those related to scientific and medical issues, which I believe are true and correct to a reasonable degree of scientific and medical certainty. I do, however, reserve the right to supplement this report and my opinions in light of any additional material or information provided to me, including any reports submitted and/or any other discovery that is taken in this case. Furthermore, if called to testify, I would plan to use various demonstrative exhibits, animations, video recordings, and/or anatomic models to show the relevant anatomy and surgical procedures and to describe my opinions as set forth in this report.

My opinions and conclusions regarding the Tension-Free Vaginal Tape product, its surgical procedure, its impact on patients and surgical colleagues, as covered throughout this report, have not been derived in isolation or are the basis of solitary data and opinion; rather, my report has been formed and influenced by multiple sources, briefly summarized as follows. My independent clinical and laboratory mesh-specific research including clinical manuscripts pertaining to female SUI, female pelvic organ prolapse, including mesh-specific complications;

animal laboratory studies regarding the effects of polypropylene mesh and host foreign body response and inflammatory response; by advanced surgical fellowship training in Voiding Dysfunction and Neurourology, which is above and beyond the normal six-year urologic surgical training and my personal surgical, clinical, and research experience implanting synthetic mesh slings; my personal surgical, clinical, and research experience as a Female Pelvic Medicine and Reconstructive surgical specialist at a high volume tertiary center managing highly complicated SUI patients and the management of mesh-related complications, including the medical and surgical revisions, removal and treatment of synthetic mesh slings complications, including complications caused by the Ethicon TVT device; my attendance and participation at national and international Urological and Gynecological surgical meetings, including, but not limited to the International Pelvic Pain Society, International Continence Society meeting, Society of Female Urology and Urodynamics meeting, American Urologic Association meeting, Canadian Urological Association meeting, UCLA State of the Art Urology meeting, European Urological Association Subsection of Female Urology and Reconstructive Urology have also helped to form my opinions. I have prepared and have given lectures specifically focused on the complexities of treating female SUI and the management of complications associated with such treatments at national and international lectures including, but not limited to the International Continence Society meeting, Society of Female Urology and Urodynamics meeting, American Urologic Association meeting, Canadian Urological Association meeting, UCLA State of the Art Urology meeting, European Urological Association Subsection of Female Urology and Reconstructive Urology. I have had personal interactions and discussion with national and international urologic, gynecologic, urogynecologic and general surgery colleagues regarding the management of SUI in women, manifestation of mesh-specific complications and the treatment of mesh-

specific complications. As part of my interest in being as educated and as up-to-date and accurate as possible, I have reviewed the readily available medical literature pertaining to the treatment of SUI and the management of its complications from sources including but not limited to medical journals and the United States National Library of Medicine and the National Institute of Health.

I am a surgical journal editor and/or reviewer for 15 urologic and/or gynecologic journals (please see Curriculum Vitae for complete listing of journals) and was named Best Reviewer in Female Urology/Incontinence/Neurourology for two consecutive years (2012-2013) for the Journal of Urology. This is the highest honor awarded by the Editor of the Journal of Urology for excellence in manuscript review and preparation.

I have also performed a systematic review of internal Ethicon documents as they pertain to surgical mesh, TVT, the TVT procedure, expected SUI surgical results, expected SUI complications and rates of SUI complications, and marketing strategies designed for my surgical colleagues in urology, gynecology and urogynecology as well as for potential SUI patients. I have also reviewed the testimony of Ethicon employees. The materials I have reviewed and relied upon to form my opinion for this report are contained throughout the report and attached as Exhibit "B".

### **III. Summary of Opinions**

- A. Background on SUI and Treatments
- B. History of Synthetic Mesh Use in Surgery
- C. The Polypropylene Mesh in the TVT Should Not Be Used in the Pelvic Floor
  - 1. Polypropylene mesh in the TVT is not inert and degrades
  - 2. The TVT mesh is Heavyweight and Small Pore causing increased tissue response, chronic inflammatory response, contraction of the mesh, fibrotic bridging, folding and curling of the mesh, and scar plate formation
  - 3. Ethicon's cutting process made the mesh even more dangerous

4. The TVT mesh tested positive for cytotoxicity which can cause cell death and complications to women and, therefore, it should not be used in the pelvic floor
  5. The TVT design is flawed because it is too difficult to properly tension the TVT device due to lack of uniformity, and the device shrinks, ropes, curls and deforms making it impossible to tension
- D. Ethicon Failed to Disclose and/or Downplayed Adverse Risks, Complications and Product Information in its Instructions for Use (“IFU”)
  - E. Ethicon Failed to Test or Conduct Appropriate Studies Related to the TVT
  - F. Ethicon Failed to consider numerous known risks and hazards of the TVT while designing the product.

#### **IV. Expert Opinions**

##### **A. Background on SUI and Treatments**

###### **1. Normal Anatomy vs. Stress Urinary Incontinence**

Female stress urinary incontinence (“SUI”), also known as intrinsic sphincter deficiency (ISD), is a relatively common condition in which a woman leaks urine when her body experiences an increase in abdominal pressure, which in turn increases the pressure on the bladder. The abdominal pressure (A.K.A. “stress”) is caused by a wide variety of activities including coughing, laughing, sneezing, jumping, bending over, picking something up, running, or any other sudden movement that increases pressure on the bladder.

In a woman, the urine leakage caused by SUI is due to factors like to weakening of the muscles that surround the urethra and/or a lack of fascial support for the urethra. The fascia below the urethra serves as a backboard to prevent the urethra from “falling down and funneling open.” SUI is much more common in women than in men, largely because of pregnancy, childbirth, menopause and hysterectomies, to mention a few. Each of these conditions cause physical changes in the fascia used to support the urethra, which in turn results or contributes to SUI. There are multiple fascias, or tissues, that support the urethra, including fascia located in



the area of the pelvic floor and endopelvic fascia. In a woman with SUI, these fascia fail to provide sufficient support for the urethra, allowing the urethra to move downward when there is a sudden increase in pressure, such as that caused by a cough or a sneeze. When this happens, urine leaks out of the urethra.

SUI can have very serious effects on a woman's physical and mental health. It is not uncommon for women with SUI to stop participating in activities they once enjoyed, such as sports and other recreational activities or experience mental illness such as depression.

## 2. Alternative/Traditional SUI Treatment Options

Stress urinary incontinence affects approximately 15% to 35% of women in population-based studies [Abrams et al]. While surgical treatments are generally safe and highly effective, women with stress incontinence symptoms may wish to avoid or defer surgery for medical or personal reasons. Further, expert consensus groups recommend that non-surgical options should be offered as first-line therapy for incontinence [Hays et al].

## 3. Behavior Modification, Pelvic Floor Therapy and Exercises

Simple lifestyle or behavioral modifications such as weight loss and/or avoidance of dietary irritants such as caffeine and nicotine are often the first line of treatment and therapy and may be the only treatment necessary. Also, pelvic floor muscle exercises (Kegel exercises) are used to strengthen the muscles surrounding the urethra so that urine is less likely to leak. These therapies require time, effort and commitment, but they do not have side effects and are often very effective.

Alternatively, pelvic floor electrical stimulation utilizes electrical current to strengthen the pelvic floor and to improve its function. Biofeedback is a treatment regimen performed under the care of a specialist and/or physical therapist. It is a safe and effective method of increasing pelvic floor strength and has a role in helping women with mild stress incontinence.

Biofeedback attempts to retrain patients on how to more appropriately use their pelvic floor muscles thereby improving their urine control. Consequently, the patient becomes more aware of her pelvic muscles and will be better able to identify and use them. Pelvic floor electrical stimulation combined with biofeedback may prove useful in that the electrical stimulation provides a passive contraction with increased awareness, via biofeedback, of pelvic muscle contractions.

#### 4. Medication

There are several medications that have been studied for the potential treatment for SUI (Topical Estrogen,  $\alpha$ -Adrenergic Agonists, Imipramine, Duloxetine,  $\beta$ -Adrenergic Antagonists, and  $\beta$ -Adrenergic Agonists). However, to date their benefit is minimal for SUI and is essentially limited to possibly benefiting overactive bladder.

#### 5. Pessaries

Pessaries have been used for thousands of years to treat pelvic organ prolapse and SUI and, prior to the advent of successful surgical options; pessaries were essentially the only viable treatment for POP and SUI. Specifically, “continence pessaries” represent an alternative or complementary non-surgical approach to the treatment of stress incontinence. These devices work by providing a platform against which the urethra can compress during strenuous activity such as lifting or coughing. There are several studies describing the effectiveness of pessaries for treatment of stress incontinence but most of these studies are based on small samples of participants with short-term follow-up, which make their results questionable. Ultimately, however, due to inherent limitations of effectiveness and complications such as vaginal pain, discharge, odor and necessity of routine medical care, most patients with SUI using pessaries discontinue using the pessary.

## 6. Surgery

Surgeons have spent hundreds of years trying to develop successful treatments for SUI. Over the course of time, several successful surgical techniques have been devised, but all of the treatments have the common component of reestablishing support for the urethra that has been weakened and damaged by childbirth, hysterectomy, obesity and age.

## 7. Marshall-Marchetti-Krantz and Burch Colposuspension

In the 1940s, the Marshall-Marchetti-Krantz (MMK) procedure was developed. The MMK procedure is a surgery in which the surgeon secures the neck of the bladder—i.e., where the bladder meets the urethra—to the pubic bone with a series of sutures. The Burch colposuspension procedure is another procedure that was developed shortly after the MMK procedure. The Burch procedure is successful in treating urinary incontinence with success rates equivalent to mid-urethral synthetic slings. The Burch procedure takes longer than a procedure to implant a synthetic mid-urethral sling, however, the long-term complications with Burch related to chronic pain and dyspareunia are minimal when compare to mid-urethral synthetic slings.

## 8. Pubovaginal Slings (Autologous/Cadaveric)

In the 1980s, a major advancement occurred with the introduction of a procedure known as the pubovaginal sling (PVS). The procedure uses harvested tissue from the tough abdominal wall tissue called abdominal fascia and then implants that tissue in the shape of a sling (hammock) around the neck of the bladder and up to the abdominal wall. Since the fascial tissue comes from the patient herself it is called “autologous” meaning tissue that comes from the same individual. The procedure rapidly rivaled the Burch colposuspension as the “gold standard” for the treatment of SUI in women. With the advent of biologic and synthetic mesh-slings the number of PVS procedures initially decreased. However, with the increasing awareness among surgeons and

patients regarding the complications (dyspareunia, life-altering pain, chronic sexual dysfunction, erosions and the others listed throughout this report) of vaginal synthetic mesh use, the PVS procedure has seen a significant resurgence. In some regions and practices around the nation, the PVS has become the mainstay of therapy. In my own personal practice, at a major tertiary referral medical center, I have abandoned essentially all synthetic mesh sling implantation due to the problems associated with complications, patients' fears, patients' refusal to have mesh inserted into their bodies and cost.<sup>1</sup>

#### B. History of Synthetic Mesh Use in General Surgery

Abdominal and thoracic wall weaknesses, called hernias, exist due to weaknesses within the abdominal wall or thoracic wall due to conditions such as birth defects, surgery, and radiation effects. Traditional hernia repair surgery evolved using sutures (stitches) to bring the native tissue together. However, due to the inherent weaknesses of the tissues, failure was common and frequently resulted in significant pain and suffering for the patient. Therefore, in the 1950s, surgical meshes for hernia repairs were introduced. Subsequently, academic presentations, surgical reports and journal manuscripts began to describe mesh-related complications such as chronic pain, abdominal wall rigidity, mesh contraction, infection, fistula formation, chronic inflammatory process and recurrence.

An abundant amount of evidence in the medical literature and basic science data has been gathered over the past two decades that indicate that there is a strong and direct relationship between postoperative mesh complications and mesh design. Reducing mesh-related complications demands a thorough understanding and knowledge of the chemical, physical and synthetic characteristics of meshes and how they react inside the human body. Based upon vast amounts of general surgery and basic science literature, there is a consensus that synthetic

meshes that are low-weight, large-pore size, high porosity, monofilament, and capable of maintaining their elasticity under load will have the better results with fewer complications. Of all the mesh characteristics, mesh stiffness, porosity and the pore size of the mesh are of critical importance.

#### 1. Synthetic Mesh Use in Pelvic Floor

Introduced in April 1997 as a treatment for female urinary stress incontinence, the ProteGen® sling was a synthetic polymer (polyester) mesh sling implant not a polypropylene mesh as is TVT. Surgeons implanted the ProteGen polyester sling underneath the urethra to provide support and to reduce SUI. Unfortunately, nearly immediately following Protogen's launch, a large number of patients began experiencing severe complications such as polyester mesh erosion through the vaginal wall, vaginal infections, vaginal discharge, vaginal bleeding, foul odor and dyspareunia. In January 1999, Boston Scientific Corporation, ProteGen's manufacturer, recalled the product due to the unusually high number of complications. In the December 1999 edition of *The Journal of Urology*, a group of respected urologists from across the United States reported their findings on those complications. These findings included a high rate of complications such as tissue erosion and urethral erosion among patients in whom the ProteGen sling was placed.

During the TVT-Retropubic's FDA submission process in the late 1990s, Ethicon used the ProteGen® sling as its predicate device despite the problems and ultimate recall discussed above.

#### 2. Mentor ObTape®

The ObTape® bladder sling was introduced in 2003 by the Mentor Corporation. The ObTape mesh sub-urethreal sling is a medical device, which was inserted through via a surgical procedure via the transobturator route for the treatment of female stress urinary incontinence.

ObTape bladder sling was used in around 36,000 women prior to its elimination from the medical device market in 2006 due to its high rate of complications. Although the Ob Tape mesh was presented as a permanent solution, a large number of women have experienced debilitating complications associated with their ObTape treatment. A 2007 study showed that over 20% of ObTape recipients experienced the extrusion of the sling through the vaginal walls [Siegal et al]. Other patients developed vaginal discharge, as well as pain during sexual intercourse as well as pelvic abscesses. Originally, it was assumed that problems with the ObTape sling stemmed from the mistakes of doctors. However, subsequent findings showed that the ObTape sling had an inherent design defect due to its use of overly dense and non-woven sling material. ObTape mesh erosions into the urethra can also result in the excretion of blood and urine. Initially, mesh erosion is typically treated with a cream prescribed by a doctor; but in many cases, the cream will not fix the mesh complication. In many mesh erosion instances, further surgery may be required to remove the mesh implant. Removal of the ObTape mesh sling may be successful in treating mesh erosion, but in some situations, even after multiple surgeries, there may be persisting complications due to mesh erosion.

### 3. TVT – Retropubic

The Gynecare TVT device is intended to be used as a pubovaginal suburethral sling for treatment of female stress urinary incontinence (SUI), caused by from urethral hypermobility and/or intrinsic sphincter deficiency. Gynecare TVT introducer, rigid catheter guide and Gynecare TVT abdominal guides and couplers are available separately and intended to facilitate the placement of the Gynecare TVT device. The reusable TVT handle and rigid catheter guide are also used to facilitate device placement.

The components to the TVT-Retropubic procedure are the TVT device, the polypropylene mesh sling attached to needles, TVT Introducer and the TVT Rigid Catheter Guide.

#### 4. TVT-Device and Prolene Mesh Sling

The TVT device is a sterile single-use device consisting of one piece of undyed Prolene® polypropylene mesh (tape) approximately 1/2 x 16 inches (1.1 x 40 centimeters), covered by a plastic sheath cut in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars. The Prolene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in Prolene polypropylene nonabsorbable surgical suture. The mesh is approximately 0.027 inches (0.7 millimeters) thick. This material “when used as a suture” has been reported to be “non-reactive and to retain its strength indefinitely” in clinical use. According to the Ethicon IFU, the Prolene mesh is knitted by a process “which interlinks each fiber junction and which provides for elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.”<sup>1</sup>

#### 5. TVT introducer

The TVT introducer is a non-sterile and reusable surgical tool for the TVT-Retropubic procedure. The introducer is constructed of stainless steel. It consists of three parts; a handle, an inserted threaded metal shaft and a synthetic rubber O-ring. The rubber O-ring prevents the shaft from falling out from the handle when the introducer is held upside down during surgical use. The introducer is intended to facilitate the passage of the TVT device from the vagina to the abdominal skin. It is connected and fixed to the needle, via the threaded end of the shaft, prior to inserting the needle with the tape.

#### 6. TVT Rigid Catheter Guide

The TVT Rigid Catheter Guide is a non-sterile, reusable instrument intended to facilitate

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<sup>1</sup> ETH.MESH.00353639, ETH.MESH.00015699 –00015706; ETH.MESH.00013506; ETH.MESH.00922443-00922445; ETH-00938; Walji Deposition p471-472; Robinson Deposition 3-14, p683-684; Kirkemo Deposition 4-18, p246-247, Ciarrocca Deposition 3-29, p264

the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley urinary catheter.

#### 7. Surgical Technique

A small anterior vaginal wall incision with lateral dissection is made under the midurethra as well as two suprapubic skin incisions. After the introducer is attached to the end of one of the needles, the device is passed paraurethrally penetrating the urogenital diaphragm passing closely behind the pubic bone up to the abdominal incision. Insertion and passage are controlled by using one finger in the vagina under the vaginal incision and fingertip control on the pelvic rim. Via use of a Foley catheter and the rigid catheter guide, the urethra and empty bladder are moved contralateral to the side of the needle passage. The procedure is then repeated on the other side. After passage of the needles, cystoscopy is performed to confirm bladder integrity. The needles are pulled upward to bring the tape (sling) loosely (i.e., without tension) under the midurethra. The needles are then separated by cutting from the tape. The plastic sheaths that surround the tape are removed. By using patient feedback (e.g., coughing with a full bladder), appropriate tension on the sling is supposed to be determined taking care to avoid over-tensioning. During this test, the vaginal incision should temporarily be closed by a gentle grip with a small forceps. Following this procedure, catheterization is not typically required.

#### C. The Old Construction Heavy Weight/Small Pore Mechanically Cut Polypropylene Mesh in the TVT Should Not Be Used in the Pelvic Floor

Because of the defective characteristics of the TVT discussed below and throughout this report, Ethicon fell below the standard of care of a reasonable and prudent medical device manufacturer. The old construction mechanically cut and laser cut mesh used in the TVT device should not be used in the pelvic floor because the risks of the device far outweigh the benefits of the device. The inadequacies of the mesh and the TVT lead to long term complications,



including but not limited to, pain, acute and chronic pelvic pain, vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, negative impact on sexual function, the risk of multiple pelvic erosions that can occur throughout one's lifetime, vaginal scarring, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, the need for multiple surgical interventions that carry with them significant risks of morbidity, the development of worsening incontinence and urinary dysfunction including urinary urgency, urinary urge incontinence, urinary retention, suprapubic pain, suprapubic numbness, pain with lifting, pain with ambulation, and pain with sitting.

1. The mesh in the TVT is not inert and degrades

As polypropylene has been used in surgery for over 50 years as a suture material, Ethicon marketed the mesh in TVT as inert. However, many published studies and internal Ethicon studies and documents show that the mesh is not inert and does degrade.<sup>2</sup> In 1987, Ethicon tested samples of explanted Prolene mesh made from the same material as the TVT mesh.<sup>3</sup> After 8 years of implantation, the testing showed that the mesh was severely cracked. In 1992, Ethicon completed a study where Prolene sutures were implanted in beagle dogs for up to seven years. These sutures were removed from the dogs and examined by Ethicon's own scientists, who

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<sup>2</sup> ETH.MESH.08315783 2012 + M CER: Reduction of the mass [of the implant] and the increase in the pore size of the mesh implant foreign body are seen to alter the inflammatory response which in turn is likely to alter tissue ingrowth... As the mass of the mesh implant is reduced and the pore size is increased the surface area exposed to the host is reduced, and the foreign body reaction to the implant is reduced.”; ETH.MESH.02589033 - 02589079; ETH-80645 – 80651; Robinson Deposition 3-13, p 120; Hinoul Deposition 4-5, p165-170; Robinson Deposition 3-13, p129-130; Kirkemo Deposition 4-18, p138; 84 Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul;165(7):665-73. Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002). Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998.; Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Biomaterials. 1998 Dec;19(24):2235-46.; Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. [ABSTRACT] Chirugr 2000;71:43-51.; Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan;2(1):103-17. Clave A, Yahi H, Hammou J, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 patients. Int Urogynecol J. 2010 Mar;21(3):261-70. Klinge et al The Ideal Mesh Klosterhalfen et al: Retrieval study at 623 human mesh explants made of polypropylene. Kwon Inflammatory Myofibroblastic tumor Birolini Mesh Cancer Sternschuss Post implantation alteration of polypropylene in humans ETH.MESH.02091873 -- abnormal chronic toxicity and doing nothing

<sup>3</sup> ETH.MESH.12831407

found surface degradation in many of the samples after 7 years of implantation.<sup>4</sup> Ethicon scientist and corporate spokesperson, Thomas Barbolt, agreed that surface degradation can occur with the TVT mesh, and that this fact was confirmed by the Ethicon studies.<sup>5</sup>

Further evidence that polypropylene mesh degrades over time was provided in 1998 by the publication of the Mary article, who studied the phenomenon of mesh degradation, and concluded the process of polypropylene cooling, where the polypropylene strand cools first on the inside and then on the outside can make the strand more susceptible to degradation on the outside.<sup>6</sup> In 2007, Costello et al., reported that polypropylene is more susceptible to degradation due to oxidation caused by inflammatory response. Using Scanning Electron Microscopy (SEM), degradation could be seen in polypropylene in the form of cracks and peeling.

Dr. Donald Ostergard, urogynecologist and founder of AUGS, created a presentation titled “Polypropylene is Not Inert in the Human Body” in which he described degradation of in vivo polypropylene.<sup>7</sup> Dr. Ostergard concluded that Prolene mesh degradation occurs by oxidation. He further concluded that a large surface area, such a piece of surgical mesh, in contrast to a suture, incites more inflammation and results in more oxidation since more macrophages are present. These macrophages then secrete hydrogen peroxide and hypochlorous acid to oxidize the mesh, which can cause the mesh to become brittle and to crack. As discussed below, these changes cause complications to patients due to the increased inflammatory response.

In a 2010 article by Clave et al., 100 explants were analyzed. Results showed a greater than 20% rate of degradation from the implants. They concluded that “for transvaginal surgery, clinical experience indicates the use of low density, large pore implants knitted from a

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<sup>4</sup> ETH.MESH.05453719

<sup>5</sup> Deposition of Thomas Barbolt, January 8, 2014, pg 409:2-13; 516:21-517:4

<sup>6</sup> Mary, Celine, et. al. Comparison of In Vivo Behavior of Polyvinylidene Fluoride and Polypropylene Sutures used in Vascular Surgery

<sup>7</sup> “Polypropylene is Not Inert in the Human Body” Presentation by Donald R. Ostergard

monofilament to facilitate tissue integration, and decrease the inflammatory response....not all types of PP implants degraded equally.” It should be noted that the lead author, Henri Clave, holds an educational position for Ethicon Europe. In fact, Ethicon’s scientists responded to that article, admitting that it was possible that the polymers may be subject to surface degradation free radicals and oxygen species in the human body, but that it did not know the clinical significance of these reactions.<sup>8</sup> Later, in 2013, the Wood study showed that polypropylene explanted from a patient showed significant oxidation of the material, and concluded that polypropylene will degrade in an oxidizing environment, such as a foreign body response in the human body.<sup>9</sup> Other authors and studies have demonstrated similar results with polypropylene in general.<sup>10</sup> In 2015, seven explants from sling devices including the TVT, were removed 4-7 years after implantation. Comparison of SEM images for explant samples with control pristine samples revealed extensive surface degradation and the formation of surface cracks in the samples, demonstrating the polypropylene fibers from mid-urethral slings are not inert over time.<sup>11</sup>

As polypropylene degrades, the inflammatory response increases and intensifies. The abraded fiber surface increases the surface area of the mesh, provides multiple areas that can effectively harbor bacteria, become brittle and creates a “barbed-wire” effect, all of which lead to

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<sup>8</sup> ETH.MESH.07205369

<sup>9</sup> Wood, et. al. Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. *J Mater Sci*: 24:1113-1122 (2013).

<sup>10</sup> Iakovlev, et al., Pathology of Explanted Transvaginal Meshes. *Intl . Science Index Vol. 8 No. 9* (2014); Martin, MK Gupta, JM Page, F Yu, JM Davidson, SA Guelcher, CL Duvall. Synthesis of a Porous, Biocompatible Tissue Engineering Scaffold Selectively Degraded by Cell-Generated Reactive Oxygen Species. *Biomaterials* 35(12):3766-76, 2014; AE Hafeman, KJ Zienkiewicz, AL Zachman, HJ Sung, LB Nanney, JM Davidson, SA Guelcher. Characterization of degradation mechanisms of biodegradable lysine-derived aliphatic polyurethanes. *Biomaterials* 32(2):419-29, 2011.

<sup>11</sup> Tzartzeva, et al. In-depth nano-investigation of vaginal mesh and tape fiber explants in women. Abstract 366 (2015);

an increased risk of an enhanced and chronic inflammatory response, as well as chronic infections due to bacterial proliferation at the mesh surface.<sup>12</sup>

The literature and internal Ethicon studies demonstrate that Ethicon's surgical polypropylene meshes oxidize, degrade, crack and peel in human tissue and become brittle. Dr. Iakovlev has also published numerous articles showing and explaining the degradation and surface cracking of polypropylene explants using histological and transmission electron microscopy approaches.<sup>13</sup>

Ethicon also knew this information before and at the time of launch of the TVT. There are Ethicon studies dating back as far as 1983 using test methods nearly identical to Dr. Iakovlev's showing in vivo degradation of the Prolene polypropylene material.<sup>14</sup> Ethicon conducted additional studies in 1985 (dog study) and in 1987 (human explants); both showing in vivo degradation and cracking of the polypropylene materials.<sup>15</sup> In fact, Ethicon had its meshes reviewed by an outside consulting company who found that its meshes degrade and that the process starts immediately.<sup>16</sup> Yet, Ethicon never performed a study to determine the clinical significance of the degradation of its mesh.

It is my opinion, to a reasonable degree of medical and scientific certainty that polypropylene degrades in the human body causing the complications discussed throughout this report to women.

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<sup>12</sup> [Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. *Int Urogynecol J*. 2011 Jan;22(1):47-52.]

<sup>13</sup> Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. *Virchows Archiv* 2014, 463(1): 35; Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. *Virchows Archiv* 2014, 463(1):35.

<sup>14</sup> ETH.MESH.15955438

<sup>15</sup> ETH.MESH.00004755; ETH.MESH.11336474; ETH.MESH.13334286

<sup>16</sup> ETH.MESH.07192929

2. The TVT mesh is Heavyweight and Small Pore causing increased tissue response, chronic inflammatory response, contraction and shrinkage of the mesh, fibrotic bridging and scar plate formation, and folding and curling of the mesh

Ethicon scientists have known for over 16 years that heavyweight, small pore meshes are associated with excessive foreign body reaction, chronic inflammation, bridging fibrosis, scar plate formation, and consequential shrinkage of the mesh.<sup>17</sup> Further, Ethicon knew that the TVT mesh is heavyweight and has small pores.<sup>18</sup> Ethicon has realized the need for decreasing complications rates from its heavyweight, small pore meshes through the development of lighter weight materials, which elicit a lower inflammatory response in the human body.<sup>19</sup> In fact, Ethicon has developed lighter weigh materials for use elsewhere in the human body, including the pelvic floor. However, today, Ethicon continues to use the heavyweight, small pore Prolene mesh, originally developed in 1974 for use in hernia surgery, for its TVT device used for SUI.<sup>20</sup> This is true despite the fact that Ethicon knows the heavyweight, small-pore meshes have a greater inflammatory response and is related to increased rates of patient complications than lightweight large pore meshes regardless of where the mesh, is located in the human body.<sup>21</sup>

The implantation of the TVT mesh creates a foreign body reaction and a chronic inflammatory response that can lead to chronic pain in the patient. The body's foreign body response to the mesh can cause a severe and chronic inflammatory reaction leading to excessive scarring in and around the mesh and the degree of this reaction is directly related to the weight

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<sup>17</sup> ETH.MESH.05479411; Klinge U., Klosterhalfen B., Birkenhauer V., Junge K., Conze J., and Schumpelick V., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model; Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surgical Innovation. 2005; 12(1):T1-T7; Cobb, W., et al. Textile Analysis of Heavy Weight, Mid-Weight, and Light Weight Polypropylene Mesh in a Porcine Ventral Hernia Model. Journal of Surgical Research 136, 1-7 (2006); Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998; 164; 965-969; Klosterhalfen, B., Junge, K., Klinge, U. The lightweight and large porous mesh concept for hernia repair. Expert Rev. Med. Devices. 2005; 2(1)

<sup>18</sup> ETH.MESH.05479411, Cobb et. al., The Argument for Lightweight Polypropylene Mesh in Hernia Repair, Deposition of Joerg Holste, July 29, 2013 40:12-15, Deposition of Brigitte Hellhammer MD., September 11, 2013 151:16-20, ETH.MESH.05479535

<sup>19</sup> ETH.MESH.01203957, Trial Testimony of Piet Hinoul, Batiste March 27, 2014 afternoon, 73:11-25

<sup>20</sup> ETH.MESH.04941016, HMESS\_ETH\_02030355,

<sup>21</sup> Deposition of Joerg Holste, July 29, 2013 95:4-11

and pore size of the mesh device.<sup>22 23 24 25</sup> Ethicon has known that clinical data have shown more chronic pain with heavyweight meshes such as the TVT mesh, than with lightweight, partially absorbable meshes. Ethicon's own medical director has stated that the presence of the foreign body, i.e. the TVT mesh, can be responsible for chronic pain syndrome in the patient.<sup>26</sup> In fact, one study has found that heavyweight meshes with small pores had to be explanted due to chronic pain more frequently than lightweight meshes with large pores.<sup>27</sup>

The foreign body reaction caused by the TVT mesh is chronic and this chronic inflammation and reaction can lead to mesh contraction and shrinkage.<sup>28</sup> Most studies show less shrinkage than heavyweight meshes, and pore size is one of the most important factors regarding mesh shrinkage.<sup>29</sup> Ethicon knew that all polypropylene meshes experience a 20-50% reduction in their initial size following implantation in the body.<sup>30</sup> Ethicon's medical director knew that the TVT mesh can shrink, and generally believed the TVT mesh would shrink approximately 30% post implantation.<sup>31</sup> The mesh contraction and shrinkage can increase the degree of foreign body reaction and mesh degradation, increasing the degree of pelvic pain and pelvic floor dysfunction such as sexual activity and urination, pain with sitting, and ambulation.<sup>32</sup>

A recent study has shown that mesh shrinkage is progressive and there is a linear evolution of the contraction rate over time, indicating that mesh contraction continues in the

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<sup>22</sup> Deposition of Piet Hinoul, April 4, 2012 99:99-99:25

<sup>23</sup> ETH.MESH.08315782

<sup>24</sup> Trial Testimony Piet Hinoul, March 27, 2014 afternoon, 27:10-17

<sup>25</sup> ETH.MESH.05916450

<sup>26</sup> ETH.MESH.01202102

<sup>27</sup> Klostherhalfen, B, Junge, K, Klinge, U, "The lightweight and large porous mesh concept for hernia repair," Expert Rev. Med. Devices, 2005 2(1)

<sup>28</sup> Deposition of Christophe Vailhe June 21, 2013 838:8-19

<sup>29</sup> ETH.MESH.02316781

<sup>30</sup> Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surgical Innovation. 200

<sup>31</sup> ETH.MESH.03910418

<sup>32</sup> De Tayrac, et. al. Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. American Journal of Surgery Vol 193, Issue 4, April 2007, p538-542

patient's body indefinitely into the future.<sup>33</sup> Vaginal mesh contraction can result in vaginal fibrosis, infection, chronic vaginal pain, chronic pelvic pain, vaginal shortening, vaginal narrowing, vaginal extrusion, adjacent organ erosion, and dyspareunia. Feiner and Maher evaluated 17 women with vaginal mesh contraction to demonstrate that the mesh caused the condition. The patients' presenting complaints included severe vaginal pain, dyspareunia, and focal tenderness over contracted portions of mesh on vaginal examination, mesh erosion, vaginal tightness, and vaginal shortening. The patients underwent surgical intervention with mobilization of mesh from underlying tissue, division of fixation arms of the central graft, and excision of contracted mesh. Fifteen of 17 (88%) patients reported a 'substantial reduction in vaginal pain following explantation, while none of 11 (64%) reported 'substantial' reduction in dyspareunia. However, despite Feiner's relative success with mesh explantation, the adverse effects of transvaginal mesh contraction caused permanent life-altering sequelae in 22-46% of patients in this study.<sup>34</sup> I personally see this type of permanent life-altering sequelae in my daily practice in patients I treat for severe complications related to mesh slings, including Ethicon's TVT device.

Polypropylene induces a rapid and acute inflammatory response and a strong scar formation. Heavyweight meshes with small pores such as the mesh in the TVT, induce an intense, chronic foreign body reaction with intensified bridging scar formation.<sup>35</sup> An increased foreign body reaction with a chronic inflammatory response and the forming of a rigid scar plate are the primary reasons for the shrinkage and contraction of meshes. Decreasing the weight of

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<sup>33</sup> Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. *Int Urogynecol J*. 2011 Jan;22(1):47-52.;

<sup>34</sup> Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. *Obstet Gynecol*. 2010 Feb;115(2 Pt 1):325-30.;

Foon R, Toozs-Hobson P, Latthe P. Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008 Dec;19(12):1697-706.

<sup>35</sup> ETH.MESH.02316781

these meshes reduces both shrinkage and the inflammatory response. A pore size of greater than 1 mm is needed to prevent the fibrotic bridging and scar plate formation.<sup>36</sup> The mesh in the TVT has a pore size that is less than 1mm after implantation.<sup>37</sup> The fact that the pore size of the TVT is not greater than 1mm in all directions prevents proper tissue integration, which can reasonably be expected to result in the development of a rigid scar plate, leading to, among other things, the potential for increased erosion, pain, nerve entrapment, and dyspareunia.

Ethicon knew as early as 1998 that the construction and weight of the Prolene mesh utilized in the production of the TVT needed to be improved due to the fact that the mesh curled and folded under tension and would not return to its original shape, remaining curled.<sup>38</sup> Ethicon embarked on the “Prolene Mesh Improvement Project” to address these problems with the mesh. Ethicon ultimately changed the original, heavyweight 1974 mesh used for flat hernia repairs by (1) changing the construction of the mesh to prevent the mesh from curling up under tension, and (2) changing the size of the fiber used in the mesh from a 6 mil fiber to a 5 mil fiber, making the mesh lighter weight.<sup>39</sup> Despite these improvements to the Prolene flat hernia mesh, Ethicon continues to use the original construction, heavier weight 6 mil Prolene mesh in the TVT product. This is true even though Ethicon knows that mesh curls under tension, and that the mesh is known for its “bad curling quality.”<sup>40</sup> Even though the initial long-term intent of the mesh improvement project was to replace the TVT mesh with the improved construction,

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<sup>36</sup> ETH.MESH.01785259; ETH.MESH.02316781; ETH.MESH.02148431 Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan;2(1):103-17; Batke deposition 08/01/012 113:3 to 114:3, 172:6 to 174:15, 118:10 to 120:25; Hellhammer deposition 09/12/13 403:18 to 404:9; 407:13-23; Holste depositions 07/29/13 51:3 to 53:6; Holste Deposition 12/14/12 89:20 to 90:21; Semin Immunopathol (2011) 33:235–243 - a Scar net formation following large pore (~3 mm) and b scar plate formation following small-pore (~0.3 mm) mesh implantation; Arnaud deposition 9/25/13 756:9 to 757:8; ETH.MESH.03021946 T-Pro Stage Gate Meeting on August 25, 2008; ETH.MESH.02587926 When the Implant Worries the Body; ETH.MESH.01752532: Mesh Design Argumentation Issues; ETH.MESH.01785259 January 17, 2010 Email re; +M relaxation; ETH.MESH.04941016 Lightweight Mesh Development

<sup>37</sup> ETH.MESH.08315783;

<sup>38</sup> ETH.MESH.09264945

<sup>39</sup> ETH.MESH.10603246, HMESH\_ETH\_00782152

<sup>40</sup> ETH.MESH.02182839, HMESH\_ETH\_02030355



lightweight mesh,<sup>41</sup> Ethicon did not use the improved material because it felt that the changed mesh would “obsolete the clinical data” they already had on the TVT product, which was a competitive advantage for the company.<sup>42</sup> An illustration of the TVT Prolene mesh curling after being placed under tension can be seen below.

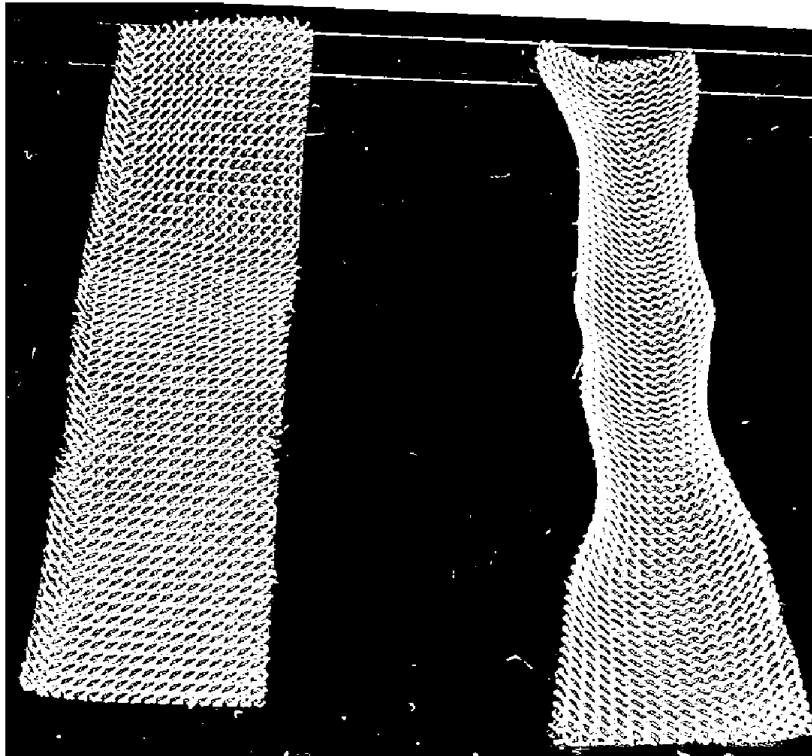


Figure 1 – Control mesh sample before and after the application of the force. A clear picture of mesh curling results.

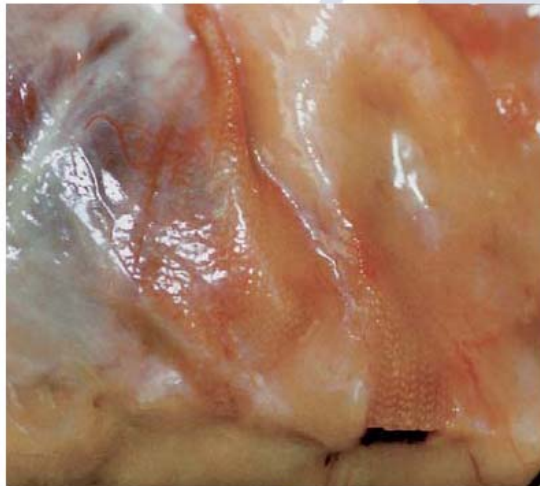
Ethicon is also aware that the heavyweight, small pore nature of the Prolene mesh makes it more likely than lightweight, large pore, partially absorbable mesh materials to “fold up” following implantation. This folding up of the mesh has also been referred to as the “potato chip” phenomena, which is caused by the increased inflammatory response to the increased

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<sup>41</sup> ETH.MESH.09264884

<sup>42</sup> ETH.MESH.03911107

weight and small pores of the current mesh.<sup>43</sup> Lightweight, large pore meshes tolerate compression much better than heavyweight Prolene mesh, which has pronounced edges and crumpling during tissue integration.<sup>44</sup> This folding of the mesh increases the amount of scar tissue formation and increases the likelihood of fibrotic bridging and scar plate formation of the mesh. In fact, in its 2004 product catalog, Ethicon advertised that its lighter weight, larger pore Vypro mesh had 60% less foreign body material compared to the Prolene mesh, and was less susceptible to the development of folded mesh post-implantation.<sup>45</sup>



Traditional polypropylene mesh. 90 days post-implantation. Fold development (in-vivo study)



Lightweight VYPRO\* II mesh. 90 days post-implantation. Fold-free incorporation (in-vivo study)

### 3. Ethicon's cutting process made the mesh even more dangerous

For Ethicon's mesh that is mechanically cut, fraying is inherent in the design of the device.<sup>46</sup> Stretching increases the probability of fraying, and when fraying occurs, the mesh narrows in places and particles break off and are lost from the mesh.<sup>47</sup> These defects in the mesh

<sup>43</sup> ETH.MESH.05918776

<sup>44</sup> ETH.MESH.05446129

<sup>45</sup> Ethicon 2004 product catalog

<sup>46</sup> ETH.MESH.00541379

<sup>47</sup> ETH.MESH.00541379

related to the mechanical cutting process lead to increased urinary retention, erosions, extrusions and exposures of the mesh into vaginal tissues, and particles of the mesh migrating into surrounding vaginal tissues causing pain.

Ethicon performed testing on TVT mechanically cut mesh samples where the mesh was stretched to 50% elongation and then measured for particle loss. Ethicon performed this test because based on their experience, 50% elongation was the estimated amount of force that is placed on the mesh during implantation.<sup>48</sup> In fact, one of Ethicon's Senior Engineers, Gene Kammerer stated that "it is my experience, after viewing many surgical procedures and performing numerous procedures on cadavers myself, that the mesh stretches approximately 50% at the maximum."<sup>49</sup> Testing done by Ethicon in 2002 showed that after elongation, some test articles lost up to 18% of their weight from particle loss.<sup>50</sup> A study published in 2004 by Pariente found that the TVT sling lost 8.5% of its particles during testing, more than 5 other competing slings.<sup>51</sup> Another researcher found the TVT easily deforms when tensioned under the urethra, which results in fraying or tanged edges and thinning of the mesh.<sup>52</sup> In fact, fraying during elongation was a major complaint of customers,<sup>53</sup> and was critical to the quality of the TVT device.<sup>54</sup> Physicians told Ethicon that particle loss from implanted mesh can migrate through vaginal tissues and cause pain.<sup>55</sup> The reason for the laser cut mesh project was to eliminate or reduce the release of these particles.<sup>56</sup>

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<sup>48</sup> ETH.MESH.01824104, ETH.MESH.00584811, ETH.MESH.00301874

<sup>49</sup> ETH.MESH.00584811; ETH.MESH.08334244

<sup>50</sup> ETH.MESH.04384185

<sup>51</sup> ETH.MESH.01221055, Pariente et.al., An independent biomechanical evaluation of commercially available suburethral slings.

<sup>52</sup> Moali et.al., Tensile properties of five commonly used mid-urethral slings relative to the TVT. Int Urogynecol J June 22, 2007

<sup>53</sup> ETH.MESH.10611169

<sup>54</sup> ETH.MESH.00301741

<sup>55</sup> ETH.MESH.05644164, ETH.MESH.03924557

<sup>56</sup> ETH.MESH.00301741

Ethicon continued to see problems with inconsistent tape width.<sup>57</sup> Doctors would report that the edges of the tape were crumbling, and that it got worse if the tape was stretched.<sup>58</sup> Ethicon knew that the mechanically cut mesh was more likely to curl and rope which reduces the area of mesh to a localized point, increasing the pressure and potentially causing urinary retention.<sup>59</sup> Ethicon also knew that the increased roping or deconstruction of the mesh knit due to the narrowing of the mesh could result in erosion.<sup>60</sup> In 2005, Ethicon tested laser cut mesh for the TVT and again performed a 50% elongation test of the material and compared that side by side with the mechanically cut mesh.<sup>61</sup> Ethicon found that that the laser cut mesh substantially reduced the roping, curling, fraying and particle loss they were seeing with the mechanically cut mesh.<sup>62</sup> However, as discussed below, laser cutting of the mesh introduced new and different problems.

The roping and fraying of the mechanically cut mesh results in increased particle loss and frayed and sharp edges, which result in erosions, extrusions, and exposures of the mesh into the vaginal tissue of patients causing pain, chronic pain, and dyspareunia. These problems, along with numerous other complications, are things I see on a daily basis in my clinical practice dealing with mesh complications, including Ethicon's TVT device. Ethicon has known that it was important to have a mesh that did not fray or have "spiky" or sharp edges in 1997 before the TVT product was even launched in the United States, when it was reported to Ethicon that a patient treated with Prolene had a vaginal erosion requiring trimming of the mesh.<sup>63</sup> Ethicon also

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<sup>57</sup> ETH.MESH.12002601

<sup>58</sup> ETH.MESH.02180833

<sup>59</sup> ETH.MESH.01822361

<sup>60</sup> ETH.MESH.06696593

<sup>61</sup> ETH.MESH.08334244-45

<sup>62</sup> ETH.MESH.00526473

<sup>63</sup> ETH.MESH.12006257

knew that ideally, the Prolene mesh should have a smooth edge,<sup>64</sup> and that the mesh in the TVT should minimize abrasion.<sup>65</sup> Ethicon received multiple reports from patients of frayed mesh extruding through vaginal tissues causing pain both for women and their sexual partners.<sup>66</sup> The laser cut mesh created smooth or beaded edges in contract to the sharp, spike-like edges of the mechanically cut mesh,<sup>67</sup> which reduced the possibility of vaginal erosion.

In 2005, Ethicon introduced laser cut mesh which decreased the likelihood of fraying mesh and in turn, substantially decreased the likelihood of these adverse events; yet Ethicon continued to sell the mechanically cut mesh for the TVT despite laser cut mesh being a safer option from the point of view of over-tensioning defects and complications. However, the laser cut mesh created another set of problems. In part due to the beaded edge, the laser cut mesh had different mechanical properties as compared to the mechanically cut mesh. Specifically, the laser cut mesh was stiffer, less flexible, and less elastic than the mechanically cut mesh.<sup>68</sup> These essential mesh properties affect how a plastic mesh performs when being implanted in the pelvic floor and change how much force the surgeon should use when implanting the mesh and setting the appropriate tension. As previously discussed, the tension in an implanted mesh can lead to complications such as pain, erosion, and damage to tissues and organs. Ethicon never warned doctors that the new laser cut mesh had different mechanical properties than the mechanically cut mesh. Instead, Ethicon assured doctors that the laser cut mesh was identical to the mechanically cut mesh.

Despite the fact that Ethicon introduced the option of laser cut mesh for the TVT in 2006, they continued to offer the mechanically cut mesh for financial reasons. The primary motivator

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<sup>64</sup> ETH.MESH.09266457

<sup>65</sup> ETH.MESH.12009276

<sup>66</sup> ETH.MESH.02620914-02620917; ETH.MESH.02620964-02620968, 02621143-02621146, 02622276-02622279,

<sup>67</sup> ETH.MESH.09656790-09656795

<sup>68</sup> Deposition of David Robinson, MD, July 25, 2013 at 507:18-508:1 & 509:6-21

for continuing to sell the mechanically cut mesh was that they did not want to make obsolete the years of clinical data that were already available on the TVT.<sup>69</sup> In fact, Ethicon employees were reluctant to change the mesh at all because they wanted to continue to rely on the clinical data already established, most notably the Ulmsten/Nilsson series of clinical studies.<sup>70</sup> Ethicon instead chose to allow both meshes to “ski on the market” with the mechanically cut mesh being offered as the “Colonel’s original recipe” in order to maximize the sales of the product, initially only offering the laser cut mesh to those customers who asked for it.<sup>71</sup>

As a result of all of the defects and problems with the mesh in the TVT discussed above, the TVT device should not be implanted into the human body for use in the treatment of SUI. These defects and problems with the mesh lead to numerous injuries, including but not limited to pain, acute and chronic pelvic pain, vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, negative impact on sexual function, the possibility of multiple pelvic erosions that can occur throughout one’s lifetime, vaginal scarring, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, need for multiple surgical interventions, development of worsening incontinence and urinary dysfunction including urinary urgency, urinary urge incontinence, urinary retention, suprapubic pain, suprapubic numbness, pain with lifting, pain with ambulation, and pain with sitting.

#### 4. Ethicon’s Prolene Mesh tested positive for Cytotoxicity

Cytotoxicity is the quality of being toxic to cells. If a woman’s tissues or organs are exposed to a cytotoxic substance, the cells can undergo necrosis and die rapidly, or they can undergo a form of controlled “cell death,” known as apoptosis<sup>72</sup> It is my understanding that it is common for medical devices to be subjected to Cytotoxicity testing before they are marketed to

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<sup>69</sup> ETH.MESH.03911107

<sup>70</sup> Deposition of Brigitte Hellhammer, MD, September 11, 2013 120-121; Deposition of Axel Arnaud, MD., July 19, 2013 35-37.

<sup>71</sup> ETH.MESH.00526473, ETH.MESH.00687820

<sup>72</sup> About Apoptosis. Apoptosis Interest group, National Institute of Health, November 13, 2009

doctors and patients. In support of its application to market the TVT in the United States, Ethicon did not perform any controlled clinical studies to determine the Cytotoxic potential of the TVT prior to marketing the device, but instead determined that the “long term clinical experience with PROLENE mesh indicated that Cytotoxicity testing would be sufficient to support the biocompatibility of this [mesh] component.”<sup>73</sup> Prior to the marketing the TVT device, the Prolene mesh had primarily been used in abdominal hernia repair, and had never before been specifically indicated for use in vaginal tissues. As a result, Ethicon’s conclusion that no new clinical or animal studies were needed to evaluate the Cytotoxic potential of the TVT mesh is questionable at best.

In fact, to this day, I am not aware of any long-term studies undertaken by Ethicon to determine whether or not the TVT mesh is clinically cytotoxic in women.<sup>74</sup> However, early clinical studies indicated that the TVT mesh did indeed have cytotoxic potential. Notably, the 2004 Wang study reported a defective healing rate of 2.2% in a series of 670 patients, and a persistent defective healing rate of 1%<sup>75</sup>. While this study was not published until 2004, Ethicon had been advised that Dr. Wang had experienced 25 erosions from the TVT mesh, which he suspected was due to the body’s rejection of the Prolene mesh in 2002.<sup>76</sup>

The initial Cytotoxicity testing of the TVT prototype device was conducted in March of 1997, and tested all components of the device together for a period of 24 hours. The results of this test indicated the mesh was severely cytotoxic.<sup>77</sup> Ethicon’s own Scotland lab performed follow-up testing, this time testing the needle, heat shrinking tube, sheath, and polypropylene mesh separately. In this test, the polypropylene mesh in the TVT again tested positive for

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<sup>73</sup> ETH.MESH.08476210

<sup>74</sup> Dr. David Robinson deposition, September 11, 2013, 1101:24-1102:5

<sup>75</sup> Wang AC, et. al. A histologic and immunohistochemical analysis of defective vaginal tape healing after continence taping procedures: A prospective case-controlled pilot study. American Journal of Obstetrics

<sup>76</sup> ETH.MESH.03736989, ETH.MESH.00409674

<sup>77</sup> ETH.MESH.06851860 at ETH.MESH.06852121

marked cytotoxicity. Ethicon did a third and final test in July of 1997, which finally provided a non-cytotoxic result for the polypropylene mesh. Ethicon relied on the results of this final, July 1997 test in support of its application to market the TVT device, and did not report the two prior positive cytotoxic test results to the FDA, surgeons, or the public. Ethicon's own Worldwide Medical Director from 2005-2010 was not aware of these positive tests during his tenure.<sup>78</sup> Notably, even the 1997 ISO elution testing showed that the polypropylene mesh in the TVT was moderate to severely cytotoxic, while the ISO agarose diffusion testing showed the mesh was non-cytotoxic. Despite the positive ISO elution testing, and the two previous tests showing the mesh was Cytotoxic, Ethicon concluded that "the long history of safe clinical use of polypropylene as a mesh and suture products suggests strongly that the material is inherently biocompatible, and the potential Cytotoxicity observed is self-limiting and minimal when compared to the implantation procedure itself."<sup>79</sup> It is my opinion that based on the 3 positive cytotoxic test results, that Ethicon failed in its duty as a reasonable medical device manufacturer by not conducting long-term studies to assess the Cytotoxic potential of the TVT mesh prior to marketing the device in women. This is particularly true in light of the fact that the Prolene mesh had never before been indicated specifically for use in vaginal tissues, and that there was only limited, short term data for 200 patients on a prototype device available at the time the device was first sold in the United States. In addition, the reports of 25 tape erosions from Dr. Wang in 2002 should have triggered an additional testing and assessment of the cytotoxic potential of the TVT mesh, but no additional cytotoxic testing was done as a result of these reports.

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<sup>78</sup> Dr. David Robinson deposition, September 11, 2013, 1094:19-1095:1.

<sup>79</sup> ETH.MESH.08476210



I have seen the clinical effects of the cytotoxic potential of the TVT mesh in my practice. When I have removed Prolene TVT mesh from a patient with a mesh erosion, the tissue surrounding the mesh frequently shows evidence of necrosis and cell death. This type of necrosis is typically due to either: toxins, infections, trauma, or some combination of the three.

5. The TVT design is flawed because there is no way to properly tension the TVT device to lack of uniformity and it shrinks, ropes, curls and deforms making it too difficult to tension properly

Proper tensioning of the TVT device is critical to ensure that the device is successful in its intended use to cure stress urinary incontinence and to prevent complications. However, the design of the TVT device is flawed because Ethicon cannot properly determine and/or instruct surgeons on the proper placement of the device and, in fact, Ethicon provides contradictory instructions on tensioning in its instructions for use.

It is known that improper tensioning of the TVT can lead to failure of the procedure, urinary retention, and well as urinary obstruction.<sup>80</sup> The fact that the cough test was necessary to properly tension the mesh was noted by Dr. Ulmsten in his original 1996 publication on the TVT, as well as the co-inventor of the TVT, professor Nilsson, who noted that there was a 15% difference in success rates between patients treated with the TVT under local anesthesia with a cough test, and under general anesthesia, where no cough test was possible.<sup>81</sup> Despite being aware of this concern, Ethicon launched the TVT with an IFU that informed physicians that the procedure could be performed under general or local anesthesia, yet did not inform physicians that the success rate was much greater if performed under local anesthesia with a cough test.

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<sup>80</sup> ETH.MESH.05222687

<sup>81</sup> ETH.MESH.0404851

Too much tension on the mesh can also lead to vaginal or urethral erosions.<sup>82</sup> In 2001, Ethicon medical directors recognized the need to have a standardized approach for tensioning the TVT and were working on a product which would avoid excessive tension on the mesh, but this product was never completed, and Ethicon never properly addressed how to instruct surgeons how to properly tension the mesh.

The IFU for the TVT provides insufficient and contradictory information on how to properly tension the TVT. In fact, Ethicon employees have acknowledged that the TVT has never truly been tension free, despite years of marketing it as such, and that they cannot accurately describe how to tension the mesh.<sup>83</sup> The IFU's Warnings and Precautions section cautions surgeons to "ensure that the tape is placed with minimal tension under the mid-urethra." Yet in the very same section, the surgeon is instructed to place the tape "tension-free" in the mid-urethral position to minimize the risk of de novo detrusor instability. Surgeons are told in the instruction section that once the tape is placed, they should pull the needles upwards "to bring the tape (sling) loosely, i.e. without tension, under the midurethra" and to adjust the tape so that leakage is limited to no more than one or two drops. The physician must put some kind of tension or force on the tape in order to limit the leakage.

The IFU's Adverse Reactions section says that over correcting, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction, yet the surgeon has been previously provided with five conflicting and confusing instructions to place the tape with (1) minimal tension, (2) tension-free, (3) loosely, (4) without tension, and (5) to adjust the tail of the TVT mesh until leakage is limited.<sup>84</sup> This leaves the physician with no clear, articulable standard on how to void the serious adverse reaction of urinary retention or urinary

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<sup>82</sup> ETH.MESH.05529653; ETH.MESH.0016113; ETH.MESH.05529274; ETH.MESH.04044797

<sup>83</sup> ETH.MESH.01784428; ETH.MESH..06861473

<sup>84</sup> TVT IFU

obstruction. Since it is generally impossible to adjust the tensioning more than 24 hours after an operation as tissue ingrowth begins to occur, a re-operation surgery is generally required to correct this adverse event. Therefore, it is particularly important for patient safety to determine and describe the proper tensioning of the device as part of the product design. In addition, IFU is silent of the fact that over tensioning can cause other adverse reactions as well, including vaginal or urethral erosion.

Moreover, Ethicon failed to inform that physicians that the mesh could shrink from 30-50% once the TVT was placed, which would affect the final placement and tensioning of the mesh, and failed to account for shrinkage in determining tensioning for the TVT.<sup>85</sup> Ethicon also failed to account for the effects that roping, curling, narrowing, and deformation of the mesh could have on tensioning. It is my opinion to a reasonable degree of medical certainty that Ethicon has failed in its duty as a reasonable medical device manufacturer by not developing and articulating clear and accurate instructions to surgeons on how to tension the mesh, rendering the device defective. It is also my opinion to a reasonable degree of medical certainty that Ethicon cannot develop and articulate clear and accurate instructions on how to properly tension the mesh as long as defects of heavyweight mesh shrinkage, roping, curling, narrowing, and deformation of the mesh exist as those defects create too many variations in the tensioning of the device to be overcome by instructions, no matter how well designed and articulated they may be.

6. The MSDS for the Prolene mesh states not to use with strong oxidizers like peroxides which can be abundantly found in the vagina

The polypropylene mesh in the TVT is made from plastic pellets supplied by Sunoco, a petrochemical company. Included with these plastic pellets is a material safety data sheet,

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<sup>85</sup> Ethicon knew that polypropylene mesh would likely shrink after implantation, and used 30% as a rule of thumb for that shrinkage. ETH.MESH.03917375. Actual shrinkage rates vary based on the individual patient, type of mesh, and location of mesh in the body.

(MSDS) which is intended to provide those handling or working with the product instructions and information on how to handle the substance in a safe matter. The MSDS for the TVT polypropylene states:

Incompatibility

The following materials are incompatible with this product: Strong oxidizers such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite, calcium hypochlorite and permanganates. Chlorine; Nitric acid;<sup>86</sup>

While the plastic used to make the TVT mesh is also used in a number of other Ethicon products, including Prolene hernia mesh and Prolene sutures, this warning is particularly important as it applies to the TVT mesh, as the TVT mesh is intended to be placed in the vagina, which is a ready and natural source of peroxides, a strong oxidizer. Peroxides are regularly produced naturally by a woman's body. The Prolene hernia mesh is not intended to be placed in vagina, and the TVT mesh contains approximately 1,000 times more plastic material than a Prolene suture, so the clinical effects of oxidization would be markedly different between a suture and the TVT mesh.

This warning in the Prolene MSDS should have triggered an investigation into the effects that the naturally occurring oxidizers in the vaginal would have on the TVT mesh prior to Ethicon's marketing of the device, particularly with regard to oxidation and degradation of the mesh, as well as inflammation caused the presence of these naturally occurring substances in a woman's vagina. At the very least, Ethicon should have passed this warning along to surgeons and patients using the TVT mesh so they could make an informed choice about whether or not to use the device. However, no such warning regarding the TVT mesh's incompatibility with strong oxidizers has been communicated in the IFU, and Ethicon never did studies specifically

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<sup>86</sup> Sunoco MSDS, 2003, 2005, 2009.

examining the clinical effect of these natural oxidizers on the TVT mesh. It is my opinion to a reasonable degree of medical certainty that Ethicon has failed in its duty as a reasonable medical device manufacturer by failing to include this warning in the IFU, and by failing to adequately study the clinical effects of the vagina's natural oxidizers on the TVT.

D. Ethicon Failed to Disclose and/or Downplayed Adverse Risks, Complications and Product Information in its Instructions for Use ("IFU") for the TVT

Ethicon's Instructions for Use ("IFU") fails to disclose important safety and risk information to physicians thereby compromising the ability for all levels of surgeons to adequately and appropriately consent their patients prior to the implantation of the TVT device. The IFU serves as the main modality for information regarding surgery. The IFU is the one document that Ethicon knew all surgeons see prior to the implantation of the TVT device.<sup>87</sup> In addition, according to Ethicon's Medical Director Piet Hinoul, physicians should be allowed to rely on the safety information in the IFU standing alone.<sup>88</sup> For this reason and according to Ethicon's own Regulatory and Medical Affairs, all risks associated with a medical device must be included in the products' IFU.<sup>89</sup> This is true so that all physicians know the safety and risk information known to a company and related to a specific product. In this case, the IFU for the TVT only lists the following information in its Adverse Risks Section for the TVT:

Adverse Reactions

- \* Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- \* Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.

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<sup>87</sup> Deposition of Dr. Richard Isenberg November 6, 2013 566:4-8

<sup>88</sup> Deposition of Dr. Piet Hinoul, January 14, 2014, 1207:18-1208:11

<sup>89</sup> Deposition of Catherine Beath, July 12, 2012, 592:7-11, Deposition of Dr. Marty Weisberg, August 9, 2013, 959:19-960:15

\* As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.

\* Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

The IFU for the TVT fails to disclose numerous adverse risks, safety information and warnings that are associated with the product, including, among others, the following: Death, pain, chronic pelvic pain, permanent dyspareunia, permanent sexual dysfunction, injury and pain to partner during sexual intercourse, negative impact on sexual function, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, surgical interventions, development of worsening incontinence and urinary dysfunction. My review of internal documents and the depositions of Ethicon employees reveals that Ethicon was aware of these risks before or at the time the TVT was first marketed and sold.<sup>90</sup> In my opinion, Ethicon's failure to warn of these significant risks makes the TVT defective.

Additionally, Ethicon not only failed to disclose certain defects related to the product in the IFU, they downplayed several of the actual defects. The defects related to the mesh that Ethicon failed to disclose in its IFU are as follows: roping, curling, fraying, particle loss, degradation, contraction and shrinkage, chronic foreign body reaction and decreased pore size. In addition, Ethicon failed to disclose risks and information related to cytotoxicity and the MSDS discussed above. Ethicon's decision to forgo adequate warnings of these defective characteristics of the TVT, also makes the TVT defective.

Ethicon also failed to include warnings in its IFU related to the increased risk of mesh extrusion in women with prior vaginal surgeries, vaginal atrophy, vaginal injury and post-

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<sup>90</sup> Deposition of Piet Hinoul, June 27, 2013 552:2-9; Deposition of Catherine Beath, July 12, 2013; 608:13-20

operative infection.<sup>91</sup> In addition, Ethicon failed to inform physicians that the TVT procedure performed under general anesthesia increases the risk of urinary retention, erosions and failure of the surgery. All of the above risks safety and warning information was known to Ethicon prior to or around the time that the TVT was first marketed. Finally, Ethicon did not tell physicians that the TVT device would not work as well in smokers or obese patients.<sup>92</sup> Ethicon failed to act like a reasonable medical device manufacturer by failing to include the above risk, safety and warning information. The failure to include this information deprived physicians of the information and prevented them from truly and fully being able to consent their patients prior implanting TVT devices.

Ethicon also downplays and misrepresents significant information in its IFU related to certain mesh properties. Despite the significant amount of data regarding mesh-related inflammatory response, the original and the revised IFU for TVT claim that implantation of Gynecare TVT mesh “elicits a minimum to slight inflammatory reaction, which is transient”. This is not true as the inflammatory response is chronic according to my clinical experience with the mesh and the testimony of Ethicon Medical Directors David Robinson and Piet Hinoul and is extensively documented in dozens of dozens of Ethicon documents.<sup>93</sup>

In addition, Ethicon states in its IFU that the mesh is not subject to degradation, which is also inconsistent with Ethicon internal studies and documents. In short, Ethicon not only failed to disclose certain risks associated with the product, it downplayed or inaccurately portrayed issues related to the mesh in the IFU. Thus, Ethicon failed to act like an appropriate medical device manufacturer in this regard. Ethicon prevented physicians from being able to have an

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<sup>91</sup> Deposition of Rick Isenberg, November 6, 2013 582:17-583:1, ETH.MESH.00159634 at 00159697; ETH.MESH.00203456. 92 ETH.MESH.00640394, Deposition of Aaron Kirkemo, January 7, 2014, 556:4-19; 556:24-557:1; 557:5-558:21

<sup>93</sup> Deposition of Dr. David Robinson, September 11, 2013, 1087:7-1089:15; Deposition of Dr. Piet Hinoul, January 14, 2014, 1192:4-1199:12; ETH.MESH.02340504 TVT IFU; ETH.MESH.00339437-442 “5 Years of Proven Performance” Feb 2002

appropriate and accurate informed consent discussion with their patients by concealing and misrepresenting this type of information. As a result, numerous patients have suffered injuries from the TVT device that were not disclosed to them as potential adverse risks related to the TVT.

Interestingly, in May 2015, Ethicon issued a new IFU which adds numerous new risks and warnings for the first time, including but not limited to acute and/or chronic pain, dyspareunia to patients and partners that may not resolve and that one or more revision surgeries maybe be necessary to treat adverse reactions.<sup>94</sup> As stated above, Ethicon had knowledge of these risks prior to the time the TVT was first marketed or sold.

E. Ethicon Failed To Conduct Appropriate Studies Related to the TVT

Ethicon has never conducted a long-term randomized controlled trial with safety as a primary endpoint.<sup>95</sup> There are also very few studies which have actually studied chronic, long-term pain with the TVT.<sup>96</sup> In addition, to my knowledge, with respect to studies performed by persons outside of Ethicon, very few are long term randomized controlled studies and none include a primary endpoint of safety.<sup>97</sup> There have also been recent studies that suggest that the studies assessing risks of synthetic mid-urethral slings to date are poor and that long term data or evidence lags behind shorter-term studies.<sup>98</sup>

Ethicon routinely relies and promotes its products based on long-term data that originates from the original Ulmsten (and later Nillson) data and studies. However, the studies lack significant data and fail to consider or inquire about many safety risks on the original patient

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<sup>94</sup> TVT IFU, May, 2015

<sup>95</sup> Trial Testimony of Piet Hinoul in Linda Batiste Trial, 3-27-14 pm 57:9-12, 57:9-12

<sup>96</sup> Deposition of Dr. David Robinson, September 11, 2013, 978:7-14

<sup>97</sup> Deposition of David Robinson, 977:2-18

<sup>98</sup> Ford, et. al. Mid-urethral sling operations for stress urinary incontinence in women (review). The Cochrane Library, DOI: 10-1002/14651858.CD006375.pub3 (2015); Blaivas, et. al. Safety considerations for synthetic sling surgery. Nat. Rev. Urol. 18 August 2015, e-publication ahead of print.



cohort. The Ulmsten/Nillson data is also biased in that Dr. Ulmsten had financial incentives to obtain certain results with his original studies and received numerous payments, consulting agreements and royalties related to the TVT and his involvement with Ethicon.

F. Ethicon Failed to Consider Numerous Known Risks and Hazards of the TVT in its Design Process

As part of its design process, Ethicon is required to look at the potential risks of the implant.<sup>99</sup> According to Ethicon's Former Medical Director, there is a very formal process related to FMEAs, failure modes and risk analysis in determining different ways that things go wrong.<sup>100</sup> In making these determinations about risks, Ethicon relies on medical expertise from urologist like me to project what potential harms might result based on experience and literature.<sup>101</sup> According to Ethicon, a risk assessment is required to take into account all of the potential harms a product can cause once implanted.<sup>102</sup>

I have reviewed the relevant risk assessment documents created as part of the design of the mechanical-cut TVT, including the Preventia risk analysis performed by Medscand AB in 2000 and the updated Risk Assessment done in 2002.<sup>103</sup> These risk assessments leave out or do not take into account numerous risks and complications related to the TVT, including roping, curling, deforming, fraying, particle loss, degradation, contraction and shrinkage, chronic foreign body reaction and decreased pore size due to its heavyweight and/or the fact that the device is impossible or difficult to remove. Based on testimony and internal documents I have reviewed and discussed above, Ethicon had knowledge of these risks at the time the TVT was launched.<sup>104</sup> As a result, Ethicon should have taken these into account during the design of the TVT and

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<sup>99</sup> Deposition of Dr. Aaron Kirkemo, January 6, 2014, 36:15-38:16

<sup>100</sup> Deposition of Dr. Aaron Kirkemo, January 6, 2014, 36:15-38:16

<sup>101</sup> Deposition of Dr. Aaron Kirkemo, January 6, 2014, 36:15-38:16

<sup>102</sup> Deposition of Scott Ciarocca, March 29, 2012, 97:23-98:21

<sup>103</sup> ETH.MESH.01317508

<sup>104</sup> Deposition of Piet Hinoul, June 27, 2013 552:2-9; Deposition of Catherine Beath, July 12, 2013; 608:13-20

should have designed out these defects or warned about them. Because Ethicon failed to do so, the risks of the TVT are too great, and outweigh the benefits of the product.

For the reasons set forth above, Ethicon fell below the standard of care of a reasonable and prudent medical device manufacturer by using the old construction mesh in the TVT device as it should not be used in the pelvic floor when implanted in this manner. These design defects of the mesh and the TVT lead to long term complications, pain, acute and chronic pelvic pain, vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, negative impact on sexual function, the possibility of multiple pelvic erosions that can occur throughout one's lifetime, vaginal scarring, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, need for multiple surgical interventions, development of worsening incontinence and urinary dysfunction including urinary urgency, urinary urge incontinence, urinary retention, suprapubic pain, suprapubic numbness, pain with lifting, pain with ambulation, and pain with sitting.

## **V. Exhibits**

My current curriculum vitae is attached as Exhibit A.

All materials that have been available to me to consider in support of my finding and opinions are included above and listed below in Exhibit B.

## **VI. Recent Testimony**

I have testified as an expert at the following trial:

*Coloplast A/S v. Generical Medical Devices*; United States District Court – Western District of Washington at Tacoma Case No. C10-227BHS

*Linda Gross et al. v. Gynecare, et al.*; Superior Court of New Jersey Law Division – Middlesex County Case No. MID-L-9131-08

*Diane Bellew v. Ethicon et al.*; United States District Court, Southern District of West Virginia  
Case No. 2:12-cv-22473

*Janice L. St. Cyr v. C.R. Bard, Inc. et al.*; United States District Court, Southern District of West  
Virginia Case No. 2:14-cv-02313

*Kathleen Stanbrough v. C.R. Bard, Inc. et al.*; United States District Court, Southern District of  
West Virginia Case No. 2:14-cv-06937

*Sheila Sutton v. C.R. Bard, Inc. et al.*; United States District Court, Southern District of West  
Virginia Case No. 2:14-cv-00105

*Pamela Ailey v Cook Medical, Inc., et al.*; United States District Court, Southern District of West  
Virginia Case No. 2:13-CV-20496

## **VII. Compensation**

I am compensated for investigation, study and consultation in the case at the rate of  
\$700.00 per hour.

February 1, 2016

DATE



DANIEL ELLIOTT, M.D.

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>  <b>THIS DOCUMENT RELATES TO WAVE 1 AND ANY SUBSEQUENT WAVE CASES</b>	<b>Master File No. 2:12-MD-02327</b>  <b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>
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**RULE 26 EXPERT REPORT OF DR. DANIEL ELLIOTT**

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## **I. Background and Qualifications**

I am an Associate Professor of Urology at Mayo Graduate School of Medicine in Rochester, Minnesota. I received an M.D. in 1993 from Loma Linda University School of Medicine in Loma Linda, California. Following graduation from medical school, I completed my surgical residency in Urology at the Mayo Graduate School of Medicine at the Mayo Clinic in 1999. I then completed a one-year advanced surgical fellowship at Baylor College of Medicine in Houston, Texas, in Neurourology, Urodynamics and Voiding Dysfunction. I then re-joined the faculty at the Mayo Clinic, where I have spent the last 15 years specializing in treating pelvic organ prolapse and urinary incontinence in women and urinary incontinence in men. I have published over 60 peer-reviewed articles and given over a hundred lectures, many of which relate to urinary incontinence and pelvic organ prolapse. A Mayo Clinic colleague and I were the first to perform robotic sacrocolpopexy surgery for the treatment of high-grade prolapse and to publish extensively on the subject. I am a frequent invited lecturer at medical and surgical conferences addressing pelvic organ prolapse and stress urinary incontinence and their evaluation, treatments, surgical options and management of complications. I have taken and passed the subspecialty credentialing process recently established by the combined boards of the American Board of Urology and American Board of Obstetrics and Gynecology in Female Pelvic Medicine and Reconstructive Surgery.

Attached, as Exhibit “A”, to this report is a copy of my current curriculum vitae, which includes an up-to-date list of my publications, presentations, awards, and other academic activities.

## **II. Basis of Opinion**

I have been asked to provide opinions regarding the subject of female stress urinary incontinence, its evaluation, treatments, surgical options and management of complications as well as to address the actions of Ethicon, Inc., Ethicon Women's Health and Urology, a Division of Ethicon, Inc., Gynecare and Johnson & Johnson (collectively referred to as Ethicon). The focus of my investigation for this report is on the Tension-Free Vaginal Tape-Obturator ("TVT-O") and, specifically, the characteristics of the product that make it defective or, in other words, that make the risks to the patient outweigh the benefits to the patients. My opinions are based on my personal knowledge, experience, and my investigation in this case. All of my opinions, and the basis of those opinions, are true and correct to the best of my knowledge and belief, including those related to scientific and medical issues, which I believe are true and correct to a reasonable degree of scientific and medical certainty. I do, however, reserve the right to supplement this report and my opinions in light of any additional material or information provided to me, including any reports submitted and/or any other discovery that is taken in this case. Furthermore, if called to testify, I would plan to use various demonstrative exhibits, animations, video recordings, and/or anatomic models to show the relevant anatomy and surgical procedures and to describe my opinions as set forth in this report.

My opinions and conclusions regarding the Tension-Free Vaginal Tape product, its surgical procedure, its impact on patients and surgical colleagues, as covered throughout this report, have not been derived in isolation or are the basis of solitary data and opinion; rather, my report has been formed and influenced by multiple sources, briefly summarized as follows. My independent clinical and laboratory mesh-specific research including clinical manuscripts pertaining to female SUI, female pelvic organ prolapse, including mesh-specific complications;



animal laboratory studies regarding the effects of polypropylene mesh and host foreign body response and inflammatory response; by advanced surgical fellowship training in Voiding Dysfunction and Neurourology, which is above and beyond the normal six-year urologic surgical training and my personal surgical, clinical, and research experience implanting synthetic mesh slings; my personal surgical, clinical, and research experience as a Female Pelvic Medicine and Reconstructive surgical specialist at a high volume tertiary center managing highly complicated SUI patients and the management of mesh-related complications, including the medical and surgical revisions, removal and treatment of synthetic mesh slings complications, including complications caused by the Ethicon TVT-O device; my attendance and participation at national and international Urological and Gynecological surgical meetings, including, but not limited to the International Pelvic Pain Society, International Continence Society meeting, Society of Female Urology and Urodynamics meeting, American Urologic Association meeting, Canadian Urological Association meeting, UCLA State of the Art Urology meeting, European Urological Association Subsection of Female Urology and Reconstructive Urology have also helped to form my opinions. I have prepared and have given lectures specifically focused on the complexities of treating female SUI and the management of complications associated with such treatments at national and international lectures including, but not limited to the International Continence Society meeting, Society of Female Urology and Urodynamics meeting, American Urologic Association meeting, Canadian Urological Association meeting, UCLA State of the Art Urology meeting, European Urological Association Subsection of Female Urology and Reconstructive Urology. I have had personal interactions and discussion with national and international urologic, gynecologic, urogynecologic and general surgery colleagues regarding the management of SUI in women, manifestation of mesh-specific complications and the treatment of mesh-

specific complications. As part of my interest in being as educated and as up-to-date and accurate as possible, I have reviewed the readily available medical literature pertaining to the treatment of SUI and the management of its complications from sources including but not limited to medical journals and the United States National Library of Medicine and the National Institute of Health.

I am a surgical journal editor and/or reviewer for 15 urologic and/or gynecologic journals (please see Curriculum Vitae for complete listing of journals) and was named Best Reviewer in Female Urology/Incontinence/Neurourology for two consecutive years (2012-2013) for the Journal of Urology. This is the highest honor awarded by the Editor of the Journal of Urology for excellence in manuscript review and preparation.

I have also performed a systematic review of internal Ethicon documents as they pertain to surgical mesh, TVT-O, the TVT-O procedure, expected SUI surgical results, expected SUI complications and rates of SUI complications, and marketing strategies designed for my surgical colleagues in urology, gynecology and urogynecology as well as for potential SUI patients. I have also reviewed the testimony of Ethicon employees. The materials I have reviewed and relied upon to form my opinion for this report are contained throughout the report and attached as Exhibit "B".

### **III. Summary of Opinions**

- A. Background on SUI and Treatments
- B. The Polypropylene Mesh in the TVT-O Should Not Be Used in the Pelvic Floor
  - 1. Polypropylene mesh in the TVT-O is not inert and degrades;
  - 2. The TVT-O mesh is Heavyweight and Small Pore causing increased tissue response, chronic inflammatory response, contraction of the mesh, fibrotic bridging, folding and curling of the mesh, and scar plate formation;
  - 3. Ethicon's cutting process made the mesh even more dangerous.

4. The TVT-O mesh tested positive for cytotoxicity which can cause cell death and complications to women and, therefore, it should not be used in the pelvic floor;
  5. The TVT-O design is flawed because it is too difficult to properly tension the TVT-O device due to lack of uniformity, and the device shrinks, ropes, curls and deforms making it impossible to tension
- C. Ethicon Failed to Disclose and/or Downplayed Adverse Risks, Complications and Product Information in its Instructions for Use (“IFU”)
  - D. Ethicon Failed to Test or Conduct Appropriate Studies Related to the TVT-O
  - E. Ethicon Failed to consider numerous known risks and hazards of the TVT-O while designing the product.

#### **IV. Expert Opinions**

##### **A. Background on SUI and Treatments**

##### **1. Normal Anatomy vs. Stress Urinary Incontinence**

Female stress urinary incontinence (“SUI”), also known as intrinsic sphincter deficiency (ISD), is a relatively common condition in which a woman leaks urine when her body experiences an increase in abdominal pressure, which in turn increases the pressure on the bladder. The abdominal pressure (A.K.A. “stress”) is caused by a wide variety of activities including coughing, laughing, sneezing, jumping, bending over, picking something up, running, or any other sudden movement that increases pressure on the bladder.

In a woman, the urine leakage caused by SUI is due to factors like to weakening of the muscles that surround the urethra and/or a lack of fascial support for the urethra. The fascia below the urethra serves as a backboard to prevent the urethra from “falling down and funneling open.” SUI is much more common in women than in men, largely because of pregnancy, childbirth, menopause and hysterectomies, to mention a few. Each of these conditions cause physical changes in the fascia used to support the urethra, which in turn results or contributes to SUI. There are multiple fascias, or tissues, that support the urethra, including fascia located in

the area of the pelvic floor and endopelvic fascia. In a woman with SUI, these fascia fail to provide sufficient support for the urethra, allowing the urethra to move downward when there is a sudden increase in pressure, such as that caused by a cough or a sneeze. When this happens, urine leaks out of the urethra.

SUI can have very serious effects on a woman's physical and mental health. It is not uncommon for women with SUI to stop participating in activities they once enjoyed, such as sports and other recreational activities or experience mental illness such as depression.

## **2. Alternative/Traditional SUI Treatment Options**

Stress urinary incontinence affects approximately 15% to 35% of women in population-based studies [Abrams et al]. While surgical treatments are generally safe and highly effective, women with stress incontinence symptoms may wish to avoid or defer surgery for medical or personal reasons. Further, expert consensus groups recommend that non-surgical options should be offered as first-line therapy for incontinence [Hays et al].

## **3. Behavior modification & Pelvic Floor Therapy & Exercises**

Simple lifestyle or behavioral modifications such as weight loss and/or avoidance of dietary irritants such as caffeine and nicotine are often the first line of treatment and therapy and may be the only treatment necessary. Also, pelvic floor muscle exercises (Kegel exercises) are used to strengthen the muscles surrounding the urethra so that urine is less likely to leak. These therapies require time, effort and commitment, but they do not have side effects and are often very effective.

Alternatively, pelvic floor electrical stimulation utilizes electrical current to strengthen the pelvic floor and to improve its function. Biofeedback is a treatment regimen performed under the care of a specialist and/or physical therapist. It is a safe and effective method of increasing pelvic floor strength and has a role in helping women with mild stress incontinence.

Biofeedback attempts to retrain patients on how to more appropriately use their pelvic floor muscles thereby improving their urine control. Consequently, the patient becomes more aware of her pelvic muscles and will be better able to identify and use them. Pelvic floor electrical stimulation combined with biofeedback may prove useful in that the electrical stimulation provides a passive contraction with increased awareness, via biofeedback, of pelvic muscle contractions.

#### **4. Medication**

There are several medications that have been studied for the potential treatment for SUI (Topical Estrogen,  $\alpha$ -Adrenergic Agonists, Imipramine, Duloxetine,  $\beta$ -Adrenergic Antagonists, and  $\beta$ -Adrenergic Agonists). However, to date their benefit is minimal for SUI and is essentially limited to possibly benefiting overactive bladder.

#### **5. Pessaries**

Pessaries have been used for thousands of years to treat pelvic organ prolapse and SUI and, prior to the advent of successful surgical options; pessaries were essentially the only viable treatment for POP and SUI. Specifically, “continence pessaries” represent an alternative or complementary non-surgical approach to the treatment of stress incontinence. These devices work by providing a platform against which the urethra can compress during strenuous activity such as lifting or coughing. There are several studies describing the effectiveness of pessaries for treatment of stress incontinence but most of these studies are based on small samples of participants with short-term follow-up, which make their results questionable. Ultimately, however, due to inherent limitations of effectiveness and complications such as vaginal pain, discharge, odor and necessity of routine medical care, most patients with SUI using pessaries discontinue using the pessary.

## **6. Surgery**

Surgeons have spent hundreds of years trying to develop successful treatments for SUI. Over the course of time, several successful surgical techniques have been devised, but all of the treatments have the common component of reestablishing support for the urethra that has been weakened and damaged by childbirth, hysterectomy, obesity and age.

## **7. Marshall-Marchetti-Krantz & Burch Colposuspension:**

In the 1940's, the Marshall-Marchetti-Krantz (MMK) procedure was developed. The MMK procedure is a surgery in which the surgeon secures the neck of the bladder—i.e., where the bladder meets the urethra—to the pubic bone with a series of sutures. The Burch colposuspension procedure is another procedure that was developed shortly after the MMK procedure. The Burch procedure is successful in treating urinary incontinence with success rates equivalent to mid-urethral synthetic slings. The Burch procedure takes longer than a procedure to implant a synthetic mid-urethral sling, however, the long-term complications with Burch related to chronic pain and dyspareunia are minimal when compare to mid-urethral synthetic slings.

## **8. Pubovaginal Slings (Autologous/Cadaveric)**

In the 1980's, a major advancement occurred with the introduction of a procedure known as the pubovaginal sling (PVS). The procedure uses harvested tissue from the tough abdominal wall tissue called abdominal fascia and then implants that tissue in the shape of a sling (hammock) around the neck of the bladder and up to the abdominal wall. Since the fascial tissue comes from the patient herself it is called “autologous” meaning tissue that comes from the same individual. The procedure rapidly rivaled the Burch colposuspension as the “gold standard” for the treatment of SUI in women. With the advent of biologic and synthetic mesh-slings the

number of PVS procedures initially decreased. However, with the increasing awareness among surgeons and patients regarding the complications (dyspareunia, life-altering pain, chronic sexual dysfunction, erosions and the others listed throughout this report) of vaginal synthetic mesh use, the PVS procedure has seen a significant resurgence. In some regions and practices around the nation, the PVS has become the mainstay of therapy. In my own personal practice, at a major tertiary referral medical center, I have abandoned essentially all synthetic mesh sling implantation due to the problems associated with complications, patients' fears, patients' refusal to have mesh inserted into their bodies and cost.

## **B. History of Synthetic Mesh Use in General Surgery**

Abdominal and thoracic wall weaknesses, called hernias, exist due to weaknesses within the abdominal wall or thoracic wall due to conditions such as birth defects, surgery, and radiation effects. Traditional hernia repair surgery evolved using sutures (stitches) to bring the native tissue together. However, due to the inherent weaknesses of the tissues, failure was common and frequently resulted in significant pain and suffering for the patient. Therefore, in the 1950's, surgical meshes for hernia repairs were introduced. Subsequently, academic presentations, surgical reports and journal manuscripts began to describe mesh-related complications such as chronic pain, abdominal wall rigidity, mesh contraction, infection, fistula formation, chronic inflammatory process and recurrence.

An abundant amount of evidence in the medical literature and basic science data has been gathered over the past two decades that indicate that there is a strong and direct relationship between postoperative mesh complications and mesh design. Reducing mesh-related complications demands a thorough understanding and knowledge of the chemical, physical and synthetic characteristics of meshes and how they react inside the human body. Based upon vast

amounts of general surgery and basic science literature, there is a consensus that synthetic meshes that are low-weight, large-pore size, high porosity, monofilament, and capable of maintaining their elasticity under load will have the better results with fewer complications. Of all the mesh characteristics, mesh stiffness, porosity and the pore size of the mesh are of critical importance.

### **1. Synthetic Mesh Use in Pelvic Floor**

Introduced in April 1997 as a treatment for female urinary stress incontinence, the ProteGen® sling was a synthetic polymer (polyester) mesh sling implant not a polypropylene mesh as is TVT. Surgeons implanted the ProteGen polyester sling underneath the urethra to provide support and to reduce SUI. Unfortunately, nearly immediately following Protogen's launch, a large number of patients began experiencing severe complications such as polyester mesh erosion through the vaginal wall, vaginal infections, vaginal discharge, vaginal bleeding, foul odor and dyspareunia. In January 1999, Boston Scientific Corporation, ProteGen's manufacturer, recalled the product due to the unusually high number of complications. In the December 1999 edition of *The Journal of Urology*, a group of respected urologists from across the United States reported their findings on those complications. These findings included a high rate of complications such as tissue erosion and urethral erosion among patients in whom the ProteGen sling was placed.

During the TVT-Retropubic's FDA submission process in the late 1990's, Ethicon used the ProteGen® sling as its predicate device despite the problems and ultimate recall discussed above. In 2003, Ethicon then used the TVT-Retropubic as its predicate device during the TVT-Obturator 510(k) submission process.



## **2. Mentor ObTape®**

The ObTape® bladder sling was introduced in 2003 by the Mentor Corporation. The ObTape mesh sub-urethreal sling is a medical device, which was inserted through via a surgical procedure via the transobturator route for the treatment of female stress urinary incontinence. ObTape bladder sling was used in around 36,000 women prior to its elimination from the medical device market in 2006 due to its high rate of complications. Although the Ob Tape mesh was presented as a permanent solution, a large number of women have experienced debilitating complications associated with their ObTape treatment. A 2007 study showed that over 20% of ObTape recipients experienced the extrusion of the sling through the vaginal walls [Siegal et al]. Other patients developed vaginal discharge, as well as pain during sexual intercourse as well as pelvic abscesses. Originally, it was assumed that problems with the ObTape sling stemmed from the mistakes of doctors. However, subsequent findings showed that the ObTape sling had an inherent design defect due to its use of overly dense and non-woven sling material. ObTape mesh erosions into the urethra can also result in the excretion of blood and urine. Initially, mesh erosion is typically treated with a cream prescribed by a doctor; but in many cases, the cream will not fix the mesh complication. In many mesh erosion instances, further surgery may be required to remove the mesh implant. Removal of the ObTape mesh sling may be successful in treating mesh erosion, but in some situations, even after multiple surgeries, there may be persisting complications due to mesh erosion.

## **3. TVT – Obturator**

The Gynecare TVT Obturator device is intended to be used as a suburethral sling for treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The device is placed with a sterile, single-patient use procedure kit consisting of two stainless steel, helical passers designed to deliver the TVT

Obturator device, and a stainless steel winged guide designed to facilitate passage of the helical passers through the dissection tract.

**a. TVT-O Device and Prolene Mesh Sling.**

The TVT device is a sterile single-use device consisting of one piece of undyed or blue Prolene® polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 centimeters), covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. The Prolene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in Prolene polypropylene nonabsorbable surgical suture. The mesh is approximately 0.027 inches (0.7 millimeters) thick. This material “when used as a suture” has been reported to be “non-reactive and to retain its strength indefinitely” in clinical use. According to the Ethicon IFU, the Prolene mesh is knitted by a process “that interlinks each fiber junction and that providing [sic] elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.”<sup>1</sup>

**b. TVT Helical Passers.**

The TVT helical passers are two stainless steel, curved wire tools with plastic handles that are preassembled as attachments to the mesh sling within the kit, and are designed to deliver the TVT Obturator device. The helical passers – one for placing the mesh sling on the left and one for placement on the right – are designed to ensure correct placement of the mesh sling. The attached plastic handles have the Gynecare logo and thumb imprint on them such that when the surgeon holds the handles properly, the logo faces the surgeon, who places his or her thumbs on the imprints.

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<sup>1</sup> ETH.MESH.00353639, ETH.MESH.00015699 –00015706; ETH.MESH.00013506; ETH.MESH.00922443-00922445; ETH-00938; Walji Deposition p471-472; Robinson Deposition 3-14, p683-684; Kirkemo Deposition 4-18, p246-247, Ciarrocca Deposition 3-29, p264.

**c. TVT Atraumatic Winged Guide**

The TVT Atraumatic Winged Guide is a sterile component of the single-use kit. The instrument is intended to facilitate the placement of the helical passers into the two incisions the surgeon has made in the vaginal mucosa.

**d. Surgical Technique**

The surgeon makes a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus. Using a “push-spread technique,” the surgeon begins blunt dissection, typically using curved scissors. Dissection continues toward the “junction” between the body of the pubic bone and the inferior pubic ramus. When that “junction” is reached, the surgeon perforates the obturator membrane. The surgeon then inserts the Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. The surgeon inserts one of the helical passers and removes the Guide. The point of the Helical Passer should exit at a previously determined exit point. Connected to the Helical Passer, the plastic tube on the end of the mesh follows through the incision in the thigh. The surgeon pulls the plastic tube until the mesh tape appears, at which point the surgeon grasps the Passer tip firmly with a clamp and rotates the plastic handle to remove it from the assembly. The procedure is then repeated on the other side. The needles are then separated by cutting from the tape. The plastic sheaths that surround the tape are removed. By using patient feedback (e.g., coughing with a full bladder), appropriate tension on the sling is supposed to be determined taking care to avoid over-tensioning.

**C. The Old Construction Heavy Weight/Small Pore Mechanically and Laser Cut Polypropylene Mesh in the TVT-O Should Not Be Used in the Pelvic Floor.**

Because of the characteristics of the TVT-O discussed below and throughout this report, it is my opinion based on my training, experience, review of the scientific studies, Ethicon documents and depositions that TVT-O mesh should not be used in the pelvic floor. The old construction mechanically cut and laser cut mesh used in the TVT-O device should not be used in the pelvic floor because the risks of the device far outweigh the benefits of the device. The inadequacies of the mesh and the TVT-O lead to long term complications, including but not limited to, pain, acute and chronic pelvic pain, vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, negative impact on sexual function, the risk of multiple pelvic erosions that can occur throughout one's lifetime, vaginal scarring, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, the need for multiple surgical interventions that carry with them significant risks of morbidity, the development of worsening incontinence and urinary dysfunction including urinary urgency, urinary urge incontinence, urinary retention, suprapubic pain, suprapubic numbness, pain with lifting, pain with ambulation, and pain with sitting.

**1. The mesh in the TVT-O is not inert and degrades**

As polypropylene has been used in surgery for over 50 years as a suture material, Ethicon marketed the mesh in TVT-O as inert. However, many published studies and internal Ethicon studies and documents show that the mesh is not inert and does degrade.<sup>2</sup> In 1987, Ethicon

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<sup>2</sup> ETH. MESH.08315783 2012 + M CER: Reduction of the mass [of the implant] and the increase in the pore size of the mesh implant foreign body are seen to alter the inflammatory response which in turn is likely to alter tissue ingrowth... As the mass of the mesh implant is reduced and the pore size is increased the surface area exposed to the host is reduced, and the foreign body reaction to the implant is reduced.”; ETH.MESH.02589033 - 02589079; ETH-80645 – 80651; Robinson Deposition 3-13, p 120; Hinoul Deposition 4-5, p165-170; Robinson Deposition 3-13, p129-130; Kirkemo Deposition 4-18, p138; 84 Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul;165(7):665-73. Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a

tested samples of explanted Prolene mesh made from the same material as the TVT-O mesh.<sup>3</sup>

After 8 years of implantation, the testing showed that the mesh was severely cracked. In 1992, Ethicon completed a study where Prolene sutures were implanted in beagle dogs for up to seven years. These sutures were removed from the dogs and examined by Ethicon's own scientists, who found surface degradation in many of the samples after 7 years of implantation.<sup>4</sup> Ethicon scientist and corporate spokesperson, Thomas Barbolt, agreed that surface degradation can occur with the TVT mesh, and that this fact was confirmed by the Ethicon studies.<sup>5</sup> Because TVT-O uses the same polypropylene mesh as TVT, surface degradation can also occur with the TVT-O.

Further evidence that polypropylene mesh degrades over time was provided in 1998 by the publication of the Mary article, who studied the phenomenon of mesh degradation, and concluded the process of polypropylene cooling, where the polypropylene strand cools first on the inside and then on the outside can make the strand more susceptible to degradation on the outside.<sup>6</sup> In 2007, Costello et al., reported that polypropylene is more susceptible to degradation due to oxidation caused by inflammatory response.<sup>7</sup> Using Scanning Electron Microscopy (SEM), degradation could be seen in polypropylene in the form of cracks and peeling.

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rat model. J. Surgical Research 103, 208-214 (2002). Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998.; Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Biomaterials. 1998 Dec;19(24):2235-46.; Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. [ABSTRACT] Chirur 2000;71:43-51.; Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan;2(1):103-17. Clave A, Yahi H, Hammou J, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 patients. Int Urogynecol J. 2010 Mar;21(3):261-70. Klinge et al The Ideal Mesh Klosterhalfen et al: Retrieval study at 623 human mesh explants made of polypropylene. Kwon Inflammatory Myofibroblastic tumor Birolini Mesh Cancer Sternschuss Post implantation alteration of polypropylene in humans ETH.MESH.02091873 -- abnormal chronic toxicity and doing nothing

<sup>3</sup> ETH.MESH.12831407.

<sup>4</sup> ETH.MESH.05453719.

<sup>5</sup> Deposition of Thomas Barbolt, January 8, 2014, pg 409:2-13; 516:21-517:4

<sup>6</sup> Mary, Celine, et. al. Comparison of In Vivo Behavior of Polyvinylidene Fluoride and Polypropylene Sutures used in Vascular Surgery

<sup>7</sup> Costello C., et al., "Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient," Surgical Innovation, 2007, 143:168- 176).

Dr. Donald Ostergard, urogynecologist and founder of AUGS, created a presentation titled “Polypropylene is Not Inert in the Human Body” in which he described degradation of in vivo polypropylene.<sup>8</sup> Dr. Ostergard concluded that Prolene mesh degradation occurs by oxidation. He further concluded that a large surface area, such a piece of surgical mesh, in contrast to a suture, incites more inflammation and results in more oxidation since more macrophages are present. These macrophages then secrete hydrogen peroxide and hypochlorous acid to oxidize the mesh, which can cause the mesh to become brittle and to crack. As discussed below, these changes cause complications to patients due to the increased inflammatory response.

In a 2010 article by Clave et al.,<sup>9</sup> 100 explants were analyzed. Results showed a greater than 20% rate of degradation from the implants. They concluded that “for transvaginal surgery, clinical experience indicates the use of low density, large pore implants knitted from a monofilament to facilitate tissue integration, and decrease the inflammatory response....not all types of PP implants degraded equally.” It should be noted that the lead author, Henri Clave, holds an educational position for Ethicon Europe. In fact, Ethicon’s scientists responded to that article, admitting that it was possible that the polymers may be subject to surface degradation free radicals and oxygen species in the human body, but that it did not know the clinical significance of these reactions.<sup>10</sup> Later, in 2013, the Wood study showed that polypropylene explanted from a patient showed significant oxidation of the material, and concluded that polypropylene will degrade in an oxidizing environment, such as a foreign body response in the

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<sup>8</sup> “Polypropylene is Not Inert in the Human Body” Presentation by Donald R. Ostergard

<sup>9</sup> Clave, A., *Polypropylene as a Reinforcement in Pelvic Surgery is Not Inert: Comparative Analysis of 100 Explants*, I Urogynecol J 2010 21:261-270.

<sup>10</sup> ETH.MESH.07205369

human body.<sup>11</sup> Other authors and studies have demonstrated similar results with polypropylene in general.<sup>12</sup> In 2015, seven explants from sling devices, including the TVT, which is the same mesh as the TVT-O, were removed 4-7 years after implantation. Comparison of SEM images for explant samples with control pristine samples revealed extensive surface degradation and the formation of surface cracks in the samples, demonstrating the polypropylene fibers from mid-urethral slings are not inert over time.<sup>13</sup>

As polypropylene degrades, the inflammatory response increases and intensifies. The abraded fiber surface increases the surface area of the mesh, provides multiple areas that can effectively harbor bacteria, become brittle and creates a “barbed-wire” effect, all of which lead to an increased risk of an enhanced and chronic inflammatory response, as well as chronic infections due to bacterial proliferation at the mesh surface.<sup>14</sup>

The literature and internal Ethicon studies demonstrate that Ethicon’s surgical polypropylene meshes oxidize, degrade, crack and peel in human tissue and become brittle. Dr. Iakovlev has also published numerous articles showing and explaining the degradation and surface cracking of polypropylene explants using histological and transmission electron microscopy approaches.<sup>15</sup>

Ethicon also knew this information before and at the time of launch of the TVT-O. There are Ethicon studies dating back as far as 1983 using test methods nearly identical to Dr.

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<sup>11</sup> Wood, et. al. Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. *J Mater Sci*: 24:1113-1122 (2013).

<sup>12</sup> Iakovlev, et al., Pathology of Explanted Transvaginal Meshes. *Intl . Science Index Vol. 8 No. 9* (2014); Martin, MK Gupta, JM Page, F Yu, JM Davidson, SA Guelcher, CL Duvall. Synthesis of a Porous, Biocompatible Tissue Engineering Scaffold Selectively Degraded by Cell-Generated Reactive Oxygen Species. *Biomaterials* 35(12):3766-76, 2014; AE Hafeman, KJ Zienkiewicz, AL Zachman, HJ Sung, LB Nanney, JM Davidson, SA Guelcher. Characterization of degradation mechanisms of biodegradable lysine-derived aliphatic polyurethanes. *Biomaterials* 32(2):419-29, 2011.

<sup>13</sup> Tzartzeva, et al. In-depth nano-investigation of vaginal mesh and tape fiber explants in women. Abstract 366 (2015);

<sup>14</sup> [Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. *Int Urogynecol J*. 2011 Jan;22(1):47-52.]

<sup>15</sup> Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. *Virchows Archiv* 2014, 463(1): 35; Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. *Virchows Archiv* 2014, 463(1):35.

Iakovlev's showing in vivo degradation of the Prolene polypropylene material.<sup>16</sup> Ethicon conducted additional studies in 1985 (dog study) and in 1987 (human explants); both showing in vivo degradation and cracking of the polypropylene materials.<sup>17</sup> In fact, Ethicon had its meshes reviewed by an outside consulting company who found that its meshes degrade and that the process starts immediately.<sup>18</sup> Yet, Ethicon never performed a study to determine the clinical significance of the degradation of its mesh.

It is my opinion, to a reasonable degree of medical and scientific certainty that polypropylene degrades in the human body causing the complications discussed throughout this report to women.

**2. The TVT-O mesh is Heavyweight and Small Pore causing increased tissue response, chronic inflammatory response, contraction and shrinkage of the mesh, fibrotic bridging and scar plate formation, and folding and curling of the mesh.**

Ethicon scientists have had data for over 16 years showing that heavyweight, small pore meshes are associated with excessive foreign body reaction, chronic inflammation, bridging fibrosis, scar plate formation, and consequential shrinkage of the mesh.<sup>19</sup> Further, Ethicon had data showing that the TVT-O mesh is heavyweight and has small pores.<sup>20</sup> Ethicon scientists expressed the need for decreasing complications rates from its heavyweight, small pore meshes through the development of lighter weight materials, which elicit a lower inflammatory response

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<sup>16</sup> ETH.MESH.15955438

<sup>17</sup> ETH.MESH.00004755; ETH.MESH.11336474; ETH.MESH.13334286

<sup>18</sup> ETH.MESH.07192929

<sup>19</sup> ETH.MESH.05479411; Klinge U., Klosterhalfen B., Birkenhauer V., Junge K., Conze J., and Schumpelick V., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model; Cobb W., Kercher K., Heniford T. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surgical Innovation. 2005; 12(1):T1-T7; Cobb, W., et al. Textile Analysis of Heavy Weight, Mid-Weight, and Light Weight Polypropylene Mesh in a Porcine Ventral Hernia Model. Journal of Surgical Research 136, 1-7 (2006); Klinge U., Klosterhalfen B., Muller M., Ottinger A., Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998; 164; 965-969; Klosterhalfen, B., Junge, K., Klinge, U. The lightweight and large porous mesh concept for hernia repair. Expert Rev. Med. Devices. 2005; 2(1)

<sup>20</sup> ETH.MESH.05479411, Cobb et. al., The Argument for Lightweight Polypropylene Mesh in Hernia Repair, Deposition of Joerg Holste, July 29, 2013 40:12-15, Deposition of Brigitte Hellhammer MD., September 11, 2013 151:16-20, ETH.MESH.05479535



in the human body.<sup>21</sup> In fact, Ethicon has developed lighter weigh materials for use elsewhere in the human body, including the pelvic floor. However, today, Ethicon continues to use the heavyweight, small pore Prolene mesh, originally developed in 1974 for use in hernia surgery, for its TVT-O device used for SUI.<sup>22</sup> This is true despite the fact that Ethicon scientists and others have demonstrated that the heavyweight, small-pore meshes have a greater inflammatory response and are related to increased rates of patient complications than lightweight large pore meshes regardless of where the mesh, is located in the human body.<sup>23</sup>

The implantation of the TVT-O mesh creates a foreign body reaction and a chronic inflammatory response that can lead to chronic pain in the patient. The body's foreign body response to the mesh can cause a severe and chronic inflammatory reaction leading to excessive scarring in and around the mesh and the degree of this reaction is directly related to the weight and pore size of the mesh device.<sup>24 252627</sup> Ethicon has known that clinical data have shown more chronic pain with heavyweight meshes such as the TVT-O mesh, than with lightweight, partially absorbable meshes. Ethicon's own medical director has stated that the presence of the foreign body, i.e. the TVT-O mesh, can be responsible for chronic pain syndrome in the patient.<sup>28</sup> In fact, one study has found that heavyweight meshes with small pores had to be explanted due to chronic pain more frequently than lightweight meshes with large pores.<sup>29</sup>

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<sup>21</sup> ETH.MESH.01203957, Trial Testimony of Piet Hinoul, Batiste March 27, 2014 afternoon, 73:11-25

<sup>22</sup> ETH.MESH.04941016, HMESH\_ETH\_02030355,

<sup>23</sup> Deposition of Joerg Holste, July 29, 2013 95:4-11

<sup>24</sup> Deposition of Piet Hinoul, April 4, 2012 99:99-99:25

<sup>25</sup> ETH.MESH.08315782

<sup>26</sup> Trial Testimony Piet Hinoul, March 27, 2014 afternoon, 27:10-17

<sup>27</sup> ETH.MESH.05916450

<sup>28</sup> ETH.MESH.01202101

<sup>29</sup> Klosterhalfen, B, Junge, K, Klinge, U, "The lightweight and large porous mesh concept for hernia repair," Expert Rev. Med. Devices, 2005 2(1)

The foreign body reaction caused by the TVT-O mesh is chronic and this chronic inflammation and reaction can lead to mesh contraction and shrinkage.<sup>30</sup> Most studies show less shrinkage than heavyweight meshes, and pore size is one of the most important factors regarding mesh shrinkage.<sup>31</sup> Ethicon knew that all polypropylene meshes experience a 20-50% reduction in their initial size following implantation in the body.<sup>32</sup> Ethicon's medical director knew that the TVT-O mesh can shrink, and generally believed the TVT-O mesh would shrink approximately 30% post implantation.<sup>33</sup> The mesh contraction and shrinkage can increase the degree of foreign body reaction and mesh degradation, increasing the degree of pelvic pain and pelvic floor dysfunction such as sexual activity and urination, pain with sitting, and ambulation.<sup>34</sup>

A recent study has shown that mesh shrinkage is progressive and there is a linear evolution of the contraction rate over time, indicating that mesh contraction continues in the patient's body indefinitely into the future.<sup>35</sup> Vaginal mesh contraction can result in vaginal fibrosis, infection, chronic vaginal pain, chronic pelvic pain, vaginal shortening, vaginal narrowing, vaginal extrusion, adjacent organ erosion, and dyspareunia. Feiner and Maher evaluated 17 women with vaginal mesh contraction to demonstrate that the mesh caused the condition. The patients' presenting complaints included severe vaginal pain, dyspareunia, and focal tenderness over contracted portions of mesh on vaginal examination, mesh erosion, vaginal tightness, and vaginal shortening. The patients underwent surgical intervention with mobilization of mesh from underlying tissue, division of fixation arms of the central graft, and excision of contracted mesh. Fifteen of 17 (88%) patients reported a 'substantial reduction in

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<sup>30</sup> Deposition of Christophe Vailhe June 21, 2013 838:8-19

<sup>31</sup> ETH.MESH.02316781

<sup>32</sup> Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surgical Innovation. 200

<sup>33</sup> ETH.MESH.03910418

<sup>34</sup> De Tayrac, et. al. Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. American Journal of Surgery Vol 193, Issue 4, April 2007, p538-542

<sup>35</sup> Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J. 2011 Jan;22(1):47-52.;

vaginal pain following explantation, while none of 11 (64%) reported ‘substantial’ reduction in dyspareunia. However, despite Feiner’s relative success with mesh explantation, the adverse effects of transvaginal mesh contraction caused permanent life-altering sequelae in 22-46% of patients in this study.<sup>36</sup> I personally see this type of permanent life-altering sequelae in my daily practice in patients I treat for severe complications related to mesh slings, including Ethicon’s TVT-O device.

Polypropylene induces a rapid and acute inflammatory response and a strong scar formation. Heavyweight meshes with small pores such as the mesh in the TVT-O, induce an intense, chronic foreign body reaction with intensified bridging scar formation.<sup>37</sup> An increased foreign body reaction with a chronic inflammatory response and the forming of a rigid scar plate are the primary reasons for the shrinkage and contraction of meshes. Decreasing the weight of these meshes reduces both shrinkage and the inflammatory response. A pore size of greater than 1 mm is needed to prevent the fibrotic bridging and scar plate formation.<sup>38</sup> The mesh in the TVT-O has a pore size that is much less than 1mm after implantation.<sup>39</sup> The fact that the pore size of the TVT-O is not greater than 1mm in all directions prevents proper tissue integration, which can reasonably be expected to result in the development of a rigid scar plate, leading to, among other things, the potential for increased erosion, pain, nerve entrapment, and dyspareunia.

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<sup>36</sup> Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. *Obstet Gynecol.* 2010 Feb;115(2 Pt 1):325-30.;

Foon R, Tooze-Hobson P, Latthe P. Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008 Dec;19(12):1697-706.

<sup>37</sup> ETH.MESH.02316781

<sup>38</sup> ETH.MESH.01785259; ETH.MESH.02316781; ETH.MESH.02148431 Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. *Expert Rev Med Devices.* 2005 Jan;2(1):103-17; Batke deposition 08/01/012 113:3 to 114:3, 172:6 to 174:15, 118:10 to 120:25; Hellhammer deposition 09/12/13 403:18 to 404:9; 407:13-23; Holste depositions 07/29/13 51:3 to 53:6; Holste Deposition 12/14/12 89:20 to 90:21; Semin Immunopathol (2011) 33:235–243 - a Scar net formation following large pore (~3 mm) and b scar plate formation following small-pore (~0.3 mm) mesh implantation; Arnaud deposition 9/25/13 756:9 to 757:8; ETH.MESH.03021946 T-Pro Stage Gate Meeting on August 25, 2008;

ETH.MESH.02587926 When the Implant Worries the Body; ETH.MESH.01752532: Mesh Design Argumentation Issues; ETH.MESH.01785259 January 17, 2010 Email re; +M relaxation; ETH.MESH.04941016 Lightweight Mesh Development

<sup>39</sup> ETH.MESH.08315783;

As early as 1998, internal Ethicon documents show that the construction and weight of the Prolene mesh utilized in the production of the TVT-O needed to be improved due to the fact that the mesh curled and folded under tension and would not return to its original shape, remaining curled.<sup>40</sup> Ethicon embarked on the “Prolene Mesh Improvement Project” to address these problems with the mesh. Ethicon ultimately changed the original, heavyweight 1974 mesh used for flat hernia repairs by (1) changing the construction of the mesh to prevent the mesh from curling up under tension, and (2) changing the size of the fiber used in the mesh from a 6 mil fiber to a 5 mil fiber, making the mesh lighter weight.<sup>41</sup> Despite these improvements to the Prolene flat hernia mesh, Ethicon continues to use the original construction, heavier weight 6 mil Prolene mesh in the TVT-O product. This is true even though Ethicon documents show that mesh curls under tension, and that the mesh is known for its “bad curling quality.”<sup>42</sup> Even though documents demonstrate that the initial long-term goal of the mesh improvement project was to replace the TVT-O mesh with the improved construction, lightweight mesh,<sup>43</sup> Ethicon did not use the improved material because using a different mesh would “obsolete the clinical data” they already had on the TVT product, which was a competitive advantage for the company.<sup>44</sup> An illustration of the TVT Prolene mesh curling after being placed under tension can be seen below.

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<sup>40</sup> ETH.MESH.09264945

<sup>41</sup> ETH.MESH.10603246, HMESH\_ETH\_00782152

<sup>42</sup> ETH.MESH.02182839, HMESH\_ETH\_02030355

<sup>43</sup> ETH.MESH.09264884

<sup>44</sup> ETH.MESH.03911107

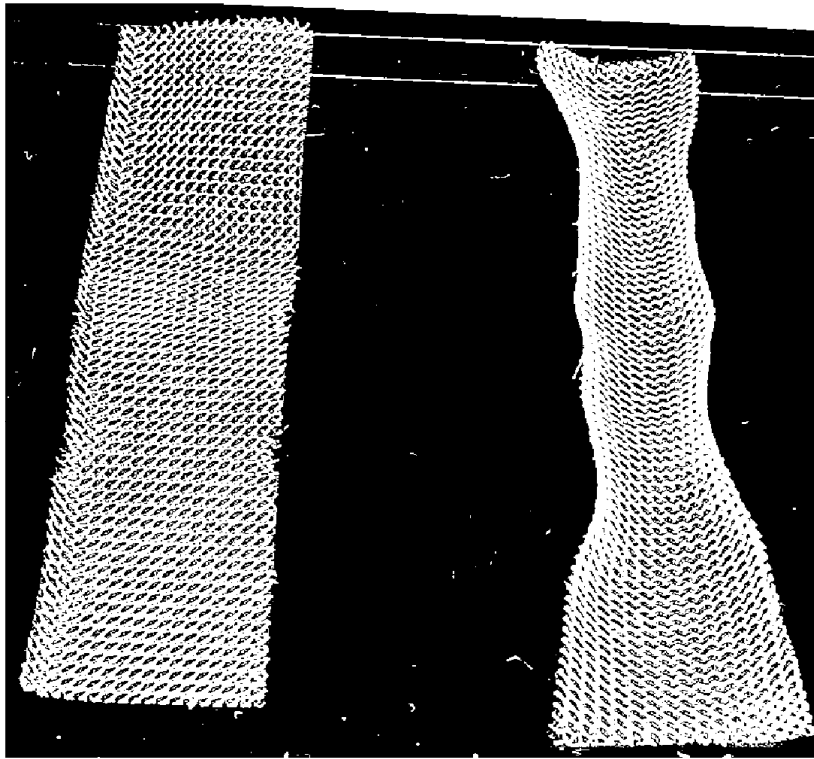


Figure 1 – Control mesh sample before and after the application of the force. A clear picture of mesh curling results.

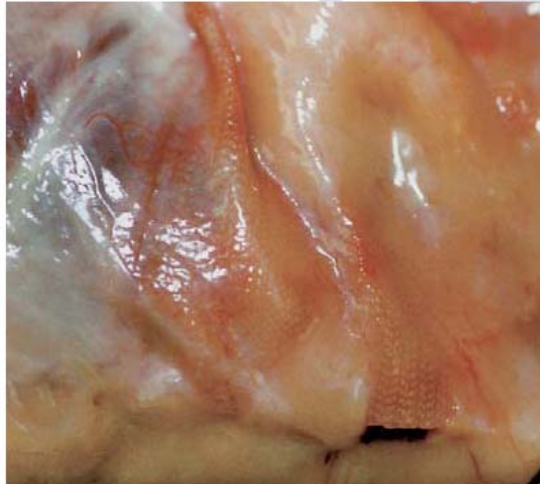
Ethicon is also aware that the heavyweight, small pore nature of the Prolene mesh makes it more likely than lightweight, large pore, partially absorbable mesh materials to “fold up” following implantation. This folding up of the mesh has also been referred to as the “potato chip” phenomena, which is caused by the increased inflammatory response to the increased weight and small pores of the current mesh.<sup>45</sup> Lightweight, large pore meshes tolerate compression much better than heavyweight Prolene mesh, which has pronounced edges and crumpling during tissue integration.<sup>46</sup> This folding of the mesh increases the amount of scar tissue formation and increases the likelihood of fibrotic bridging and scar plate formation of the mesh. In fact, in its 2004 product catalog, Ethicon advertised that its lighter weight, larger pore

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<sup>45</sup> ETH.MESH.05918776

<sup>46</sup> ETH.MESH.05446129

Vypro mesh had 60% less foreign body material compared to the Prolene mesh, and was less susceptible to the development of folded mesh post-implantation.<sup>47</sup>



Traditional polypropylene mesh. 90 days post-implantation. Fold development (in-vivo study)



Lightweight VYPRO\* II mesh. 90 days post-implantation. Fold-free incorporation (in-vivo study)

### 3. Ethicon's cutting process made the mesh even more dangerous.

For Ethicon's mesh that is mechanically cut, fraying is an inherent defect in the design of the device.<sup>48</sup> Stretching increases the probability of fraying, and when fraying occurs, the mesh narrows in places and particles break off and are lost from the mesh.<sup>49</sup> These defects in the mesh related to the mechanical cutting process lead to increased urinary retention, erosions, infections, extrusions and exposures of the mesh into vaginal tissues, and particles of the mesh migrating into surrounding vaginal tissues causing pain.

Ethicon performed testing on TVT mechanically cut mesh samples where the mesh was stretched to 50% elongation and then measured for particle loss. Ethicon performed this test because based on their experience, 50% elongation was the estimated amount of force that is

<sup>47</sup> Ethicon 2004 product catalog

<sup>48</sup> ETH.MESH.00541379

<sup>49</sup> ETH.MESH.00541379

placed on the mesh during implantation.<sup>50</sup> In fact, one of Ethicon's Senior Engineers, Gene Kammerer stated that "it is my experience, after viewing many surgical procedures and performing numerous procedures on cadavers myself, that the mesh stretches approximately 50% at the maximum."<sup>51</sup> Testing done by Ethicon in 2002 showed that after elongation, some test articles lost up to 18% of their weight from particle loss.<sup>52</sup> A study published in 2004 by Pariente found that the TVT sling lost 8.5% of its particles during testing, more than 5 other competing slings.<sup>53</sup> Another researcher found the TVT easily deforms when tensioned under the urethra, which results in fraying or tanged edges and thinning of the mesh.<sup>54</sup> In fact, fraying during elongation was a major complaint of customers,<sup>55</sup> and was critical to the quality of the TVT device.<sup>56</sup> Physicians told Ethicon that particle loss from implanted mesh can migrate through vaginal tissues and cause pain.<sup>57</sup> The reason for the laser cut mesh project was to eliminate or reduce the release of these particles.<sup>58</sup>

These issues which all existed with the TVT device were exacerbated with the TVT-O device because of the different path used to insert the device. In particular, physicians reported more difficulty removing the plastic sheath from the in-place mesh. This, in turn, led to increased tension on the mesh leading to more fraying, particle loss, roping and curling and decreased pore size. These can all lead to potential adverse events associated with tape tensioning, such as erosion, fibrotic bridging, retention, extrusion, pain, and nerve damage

During the development of the TVT-O, the inventor, Professor de Leval, used the "Babcock technique" to ensure that the tension on the mesh was proper, utilizing a Babcock

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<sup>50</sup> ETH.MESH.01824104, ETH.MESH.00584811, ETH.MESH.00301874

<sup>51</sup> ETH.MESH.00584811; ETH.MESH.08334244

<sup>52</sup> ETH.MESH.04384185

<sup>53</sup> ETH.MESH.01221055, Pariente et.al., An independent biomechanical evaluation of commercially available suburethral slings.

<sup>54</sup> Moali et.al., Tensile properties of five commonly used mid-urethral slings relative to the TVT. Int Urogynecol J June 22, 2007

<sup>55</sup> ETH.MESH.10611169

<sup>56</sup> ETH.MESH.00301741

<sup>57</sup> ETH.MESH.05644164, ETH.MESH.03924557

<sup>58</sup> ETH.MESH.00301741



clamp to hold the mesh while he pulled off the sheath.<sup>59</sup> Ethicon refused to include the Babcock technique in the IFU or even to alert physicians that the TVT-O created unique sheath removal/tensioning issues.

Predictably, when Ethicon began marketing the TVT-O, complaints about sheath removal began to come in<sup>60</sup> and were widespread.<sup>61</sup> The Marketing Director and Co-Lead of the TVT-O Project noted her concerns that it was a worldwide (“WW”) problem.<sup>62</sup> Ethicon refused to formally address the problem through changes to the IFU or Procedural steps (for example by adding the Babcock technique used by the inventor of TVT-O) leaving many physicians in the dark about why the sheath removal problems were occurring and what they could do about it.<sup>63</sup> Most importantly, without a proper fix, the tension-related defects and complications continued.

Ethicon continued to see problems with inconsistent tape width.<sup>64</sup> Doctors would report that the edges of the tape were crumbling, and that it got worse if the tape was stretched.<sup>65</sup> Ethicon had reports showing that the mechanically cut mesh was more likely to curl and rope which reduces the area of mesh to a localized point, increasing the pressure and potentially causing urinary retention.<sup>66</sup> Ethicon’s Dan Lamont admitted that the fraying of the mesh was a

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<sup>59</sup> ETH.MESH.00862727 (June 2, 2003 email from Dan Smith to others) (“Professor deLeval uses a Babcock clamp to place the TVT mesh tension free. We are not going to use this method at this time, however we discussed doing tests to ensure that the mesh is not damaged.... The reasons for use are as follows: 1st the mesh is maintained flat and cannot curl, 2nd the mesh in the 2-3 mm loop is maintained tension free during the adjustment phase of mesh insertion and 3rd the clamp is used as the guide and support as the plastic is removed to prevent over-tensioning.”).

<sup>60</sup> ETH.MESH.06884516 (“Sheath Removal problem: Dr. Jensen indicates that the issues began almost immediately when he converted to TVT-O (estimated late January/early February).”).

<sup>61</sup> ETH.MESH.01815505 at 2 (“[T]he [sheath removal] issues experienced by Dr. Feagins are not unique to the Dallas market....they are being experienced by physicians all over the country and are creating serious challenges for the sales representatives.”).

<sup>62</sup> ETH.MESH.01815505 at 8 (“From my perspective I strongly believe we have variability issues.... Having been in the OR with many surgeons the ease or difficulty of sheath removal can vary immensely.... Having spent time more time in the US this week this is a WW issue and not market specific.”).

<sup>63</sup> ETH.MESH.06881576 (“I hear what you are saying about introducing it in the procedural steps, however, what we include in the procedural steps has to reflect the IFU. Our hesitancy about doing this for launch was because we were not sure of any potential damage to the mesh caused by the babcock.”).

<sup>64</sup> ETH.MESH.12002601

<sup>65</sup> ETH.MESH.02180833

<sup>66</sup> ETH.MESH.01822361



“defect” of the mesh.<sup>67</sup> Ethicon also had data showing that the increased roping or deconstruction of the mesh knit due to the narrowing of the mesh could result in erosion.<sup>68</sup>

In 2005, Ethicon tested laser cut mesh for the TVT and again performed a 50% elongation test of the material and compared that side by side with the mechanically cut mesh.<sup>69</sup> The testing showed that that the laser cut mesh substantially reduced the roping, curling, fraying and particle loss they were seeing with the mechanically cut mesh.<sup>70</sup> However, as discussed below, laser cutting of the mesh introduced new and different problems.

The roping and fraying of the mechanically cut mesh results in increased particle loss and frayed and sharp edges, increased inflammation, and increased and exacerbated infections which all result in erosions, extrusions and exposures of the mesh into the vaginal tissue, chronic pain, and dyspareunia. These problems, along with numerous other complications, are things I see on a daily basis in my clinical practice dealing with mesh complications, including Ethicon’s TVT-O device. Internal Ethicon documents reflect that it was important to have a mesh that did not fray or have “spiky” or sharp edges in 1997 before the TVT product was even launched in the United States, when it was reported to Ethicon that a patient treated with Prolene had a vaginal erosion requiring trimming of the mesh.<sup>71</sup> The scientific data also showed that ideally, the Prolene mesh should have a smooth edge,<sup>72</sup> and that the mesh in the TVT should minimize abrasion.<sup>73</sup> Ethicon received multiple reports from patients of frayed mesh extruding through vaginal tissues causing pain both for women and their sexual partners.<sup>74</sup> The laser cut mesh created smooth or beaded edges in contract to the sharp, spike-like edges of the mechanically cut

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<sup>67</sup> Lamont Depo. (September 11, 2013) at 15:16-16:10.

<sup>68</sup> ETH.MESH.06696593

<sup>69</sup> ETH.MESH.08334244-45

<sup>70</sup> ETH.MESH.00526473

<sup>71</sup> ETH.MESH.12006257

<sup>72</sup> ETH.MESH.09266457

<sup>73</sup> ETH.MESH.12009276

<sup>74</sup> ETH.MESH.02620914-02620917; ETH.MESH.02620964-02620968, 02621143-02621146, 02622276-02622279,

mesh,<sup>75</sup> which, all other things being equal, could reduce the possibility of vaginal erosion. Only, not all else was equal.

In 2005, Ethicon introduced laser cut mesh which decreased the likelihood of fraying mesh and in turn, substantially decreased the likelihood of these adverse events caused by fraying, particle loss, roping, deformation and sharp edges; yet Ethicon continued to sell the mechanically cut mesh for the TVT-O despite laser cut mesh being a safer option from the point of view of over-tensioning defects and complications. However, the laser cut mesh created another set of problems. In part due to the hard beaded edge, the laser cut mesh had different mechanical properties as compared to the mechanically cut mesh. Specifically, the laser cut mesh was stiffer, less flexible, and less elastic than the mechanically cut mesh.<sup>76</sup> These essential mesh properties affect how a plastic mesh performs when being implanted in the pelvic floor and change how much force the surgeon should use when implanting the mesh and setting the appropriate tension. As previously discussed, the tension in an implanted mesh can lead to complications such as pain, erosion, and damage to tissues and organs. Ethicon never warned doctors that the new laser cut mesh had different mechanical properties than the mechanically cut mesh. Instead, Ethicon assured doctors that the laser cut mesh was identical to the mechanically cut mesh.

Despite the fact that Ethicon introduced the option of laser cut mesh for the TVT and TVT-O, it continued to offer the mechanically cut mesh for financial reasons. The primary motivator for continuing to sell the mechanically cut mesh was that they did not want to make obsolete the years of clinical data that were already available on the TVT.<sup>77</sup> In fact, Ethicon employees were reluctant to change the mesh at all because they wanted to continue to rely on

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<sup>75</sup> ETH.MESH.09656790-09656795

<sup>76</sup> Deposition of David Robinson, MD, July 25, 2013 at 507:18-508:1 & 509:6-21

<sup>77</sup> ETH.MESH.03911107

the clinical data already established, most notably the Ulmsten/Nilsson series of clinical studies.<sup>78</sup> Ethicon instead chose to allow both meshes to “ski on the market” with the mechanically cut mesh being offered as the “Colonel’s original recipe” in order to maximize the sales of the product, initially only offering the laser cut mesh to those customers who asked for it.<sup>79</sup>

As a result of all of the defects and problems with the mesh discussed above, the TVT-O device should not be implanted into the human body for use in the treatment of SUI. These defects and problems with the mesh lead to numerous injuries, including but not limited to pain, acute and chronic pelvic pain, vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, negative impact on sexual function, the possibility of multiple pelvic erosions that can occur throughout one’s lifetime, vaginal scarring, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, need for multiple surgical interventions, development of worsening incontinence and urinary dysfunction including urinary urgency, urinary urge incontinence, urinary retention, suprapubic pain, suprapubic numbness, pain with lifting, pain with ambulation, and pain with sitting.

#### **4. Ethicon’s Prolene Mesh tested positive for Cytotoxicity**

Cytotoxicity is the quality of being toxic to cells. If a woman’s tissues or organs are exposed to a cytotoxic substance, the cells can undergo necrosis and die rapidly, or they can undergo a form of controlled “cell death,” known as apoptosis.<sup>80</sup> It is my understanding that it is common for medical devices to be subjected to cytotoxicity testing before they are marketed to doctors and patients. In support of its application to market the TVT in the United States, Ethicon did not perform any controlled clinical studies to determine the cytotoxic potential of the

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<sup>78</sup> Deposition of Brigitte Hellhammer, MD, September 11, 2013 120-121; Deposition of Axel Arnaud, MD., July 19, 2013 35-37.

<sup>79</sup> ETH.MESH.00526473, ETH.MESH.00687820

<sup>80</sup> About Apoptosis. Apoptosis Interest group, National Institute of Health, November 13, 2009

TVT prior to marketing the device, but instead determined that the “long term clinical experience with PROLENE mesh indicated that Cytotoxicity testing would be sufficient to support the biocompatibility of this [mesh] component.”<sup>81</sup> Regarding the biocompatibility of the TVT-O mesh in its 510(k), Ethicon then stated the mesh was the same as the TVT mesh and did not perform any additional testing. Prior to the marketing the TVT device, the Prolene mesh had primarily been used in abdominal hernia repair, and had never before been specifically indicated for use in vaginal tissues. As a result, Ethicon’s conclusion that no new clinical or animal studies were needed to evaluate the cytotoxic potential of the TVT mesh is not based on sound science.

In fact, to this day, I am not aware of any long-term studies undertaken by Ethicon to determine whether or not the TVT and TVT-O mesh is clinically cytotoxic in women.<sup>82</sup> However, early clinical studies indicated that the TVT mesh did indeed have cytotoxic potential. Notably, the 2004 Wang study reported a defective healing rate of 2.2% in a series of 670 patients, and a persistent defective healing rate of 1%.<sup>83</sup> While this study was not published until 2004, Ethicon had been advised that Dr. Wang had experienced 25 erosions from the TVT mesh, which he suspected was due to the body’s rejection of the Prolene mesh in 2002.<sup>84</sup>

The initial Cytotoxicity testing of the TVT prototype device was conducted in March of 1997, and tested all components of the device together for a period of 24 hours. The results of this test indicated the mesh was severely cytotoxic.<sup>85</sup> Ethicon’s own Scotland lab performed follow-up testing, this time testing the needle, heat shrinking tube, sheath, and polypropylene mesh separately. In this test, the polypropylene mesh in the TVT again tested positive for

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<sup>81</sup> ETH.MESH.08476210

<sup>82</sup> Dr. David Robinson deposition, September 11, 2013, 1101:24-1102:5

<sup>83</sup> Wang AC, et. al. A histologic and immunohistochemical analysis of defective vaginal tape healing after continence taping procedures: A prospective case-controlled pilot study. American Journal of Obstetrics

<sup>84</sup> ETH.MESH.03736989, ETH.MESH.00409674

<sup>85</sup> ETH.MESH.06851860 at ETH.MESH.06852121

marked cytotoxicity. Ethicon did a third and final test in July of 1997, which finally provided a non-cytotoxic result for the polypropylene mesh. Ethicon relied on the results of this final, July 1997 test in support of its application to market the TVT device, and did not report the two prior positive cytotoxic test results to the FDA, surgeons, or the public. Ethicon's own Worldwide Medical Director from 2005-2010 was not aware of these positive tests during his tenure.<sup>86</sup> Notably, even the 1997 ISO elution testing showed that the polypropylene mesh in the TVT was moderate to severely cytotoxic, while the ISO agarose diffusion testing showed the mesh was non-cytotoxic. Despite the positive ISO elution testing, and the two previous tests showing the mesh was Cytotoxic, Ethicon concluded that "the long history of safe clinical use of polypropylene as a mesh and suture products suggests strongly that the material is inherently biocompatible, and the potential Cytotoxicity observed is self-limiting and minimal when compared to the implantation procedure itself."<sup>87</sup> It is my opinion, based on my training, experience, review of the scientific literature and Ethicon's documents and depositions, that based on the 3 positive cytotoxic test results, that Ethicon should have conducted long-term studies to assess the Cytotoxic potential of the TVT-O mesh prior to marketing the device in women. This is particularly true in light of the fact that the Prolene mesh had never before been indicated specifically for use in vaginal tissues, and that there was only limited, short term data for 200 patients on a prototype device available at the time the device was first sold in the United States. In addition, the reports of 25 tape erosions from Dr. Wang in 2002 should have triggered an additional testing and assessment of the cytotoxic potential of the TVT and TVT-O mesh, but no additional cytotoxic testing was done as a result of these reports.

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<sup>86</sup> Dr. David Robinson deposition, September 11, 2013, 1094:19-1095:1.

<sup>87</sup> ETH.MESH.08476210

I have seen the clinical effects of the cytotoxic potential of the TVT and TVT-O mesh in my practice. When I have removed Prolene TVT and TVT-O mesh from patients with mesh erosion, the tissue surrounding the mesh frequently shows evidence of necrosis and cell death. This type of necrosis is typically due to either: toxins, infections, trauma, or some combination of the three.

**5. The TVT-O design is flawed because there is no way to properly tension the TVT-O device to lack of uniformity and it shrinks, ropes, curls and deforms making it too difficult to tension properly**

Proper tensioning of the TVT-O device is critical to ensure that the device is successful in its intended use to cure stress urinary incontinence and to prevent complications. However, the design of the TVT-O device is flawed because Ethicon cannot properly determine and/or instruct surgeons on the proper placement of the device and, in fact, Ethicon provides contradictory instructions on tensioning in its instructions for use.

It is known that improper tensioning of the TVT and TVT-O devices can lead to failure of the procedure, urinary retention, and well as urinary obstruction.<sup>88</sup> The fact that the cough test was necessary to properly tension the mesh was noted by Dr. Ulmsten in his original 1996 publication on the TVT, as well as the co-inventor of the TVT, professor Nilsson, who noted that there was a 15% difference in success rates between patients treated with the TVT under local anesthesia with a cough test, and under general anesthesia, where no cough test was possible.<sup>89</sup> Despite being aware of this concern, Ethicon launched the TVT with an IFU that informed physicians that the procedure could be performed under general or local anesthesia, yet did not inform physicians that the success rate was much greater if performed under local anesthesia with a cough test. The TVT-O IFU repeated this flaw.

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<sup>88</sup> ETH.MESH.05222687

<sup>89</sup> ETH.MESH.0404851

Too much tension on the mesh can also lead to vaginal or urethral erosions.<sup>90</sup> In 2001, Ethicon medical directors were working on a product to create a standardized approach for tensioning the TVT and which would avoid excessive tension on the mesh, but this product was never completed, and Ethicon never properly addressed how to instruct surgeons how to properly tension the mesh.

The IFU for the TVT-O provides insufficient and contradictory information on how to properly tension the TVT-O. In fact, Ethicon employees have acknowledged that the TVT has never truly been tension free, despite years of marketing it as such, and that they cannot accurately describe how to tension the mesh.<sup>91</sup> The IFU's Warnings and Precautions section cautions surgeons to "ensure that the tape is placed with no tension under the mid-urethra." The surgeon is instructed to "position the tape loosely e.g. without tension" in the mid-urethral position and to adjust the tape so that leakage is limited to a few drops of urine. The physician must put some kind of tension or force on the tape in order to limit the leakage.

The IFU's Adverse Reactions section says that over correcting, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction, yet the surgeon has been previously provided with five conflicting and confusing instructions to place the tape with (1) tension-free, (2) loosely, (3) without tension, and (5) to adjust the mesh until leakage is limited.<sup>92</sup> This leaves the physician with no clear, articulable standard on how to void the serious adverse reaction of urinary retention or urinary obstruction. As noted above, all of these concerns were further exacerbated by the difficulties in removing the plastic sheath for the TVT-O device. Since it is generally impossible to adjust the tensioning more than 24 hours after an operation as tissue ingrowth begins to occur, a re-operation surgery is generally required to

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<sup>90</sup> ETH.MESH.05529653; ETH.MESH.0016113; ETH.MESH.05529274; ETH.MESH.04044797

<sup>91</sup> ETH.MESH.01784428; ETH.MESH..06861473

<sup>92</sup> TVT-O IFU.

correct this adverse event. Therefore, it is particularly important for patient safety to determine and describe the proper tensioning of the device as part of the product design. In addition, IFU is silent of the fact that over tensioning can cause other adverse reactions as well, including vaginal or urethral erosion.

Moreover, Ethicon failed to inform that physicians that the mesh could shrink from 30-50% once the TVT was placed, which would affect the final placement and tensioning of the mesh, and failed to account for shrinkage in determining tensioning for the TVT-O.<sup>93</sup> Ethicon also failed to account for the effects that roping, curling, narrowing, and deformation of the mesh could have on tensioning.

It is my opinion to a reasonable degree of medical certainty that Ethicon failed to develop and articulate clear and accurate instructions to surgeons on how to tension the mesh. It is also my opinion to a reasonable degree of medical certainty that Ethicon cannot develop and articulate clear and accurate instructions on how to properly tension the mesh as long as defects of heavyweight mesh shrinkage, roping, curling, narrowing, and deformation of the mesh exist as those defects create too many variations in the tensioning of the device to be overcome by instructions, no matter how well designed and articulated they may be.

**6. The MSDS for the Prolene mesh states not to use with strong oxidizers like peroxides which can be abundantly found in the vagina**

The polypropylene mesh in the TVT and TVT-O is made from plastic pellets supplied by Sunoco, a petrochemical company. Included with these plastic pellets is a material safety data sheet, (MSDS) which is intended to provide those handling or working with the product

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<sup>93</sup> Ethicon scientists determined polypropylene mesh would likely shrink after implantation, and used 30% as a rule of thumb for that shrinkage. ETH.MESH.03917375. Actual shrinkage rates vary based on the individual patient, type of mesh, and location of mesh in the body.



instructions and information on how to handle the substance in a safe matter. The MSDS for the TVT and TVT-O polypropylene states:

Incompatibility

The following materials are incompatible with this product: Strong oxidizers such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite, calcium hypochlorite and permanganates. Chlorine; Nitric acid;<sup>94</sup>

While the plastic used to make the TVT-O mesh is also used in a number of other Ethicon products, including Prolene hernia mesh and Prolene sutures, this warning is particularly important as it applies to the TVT-O mesh, as the TVT-O mesh is intended to be placed in the vagina, which is a ready and natural source of peroxides, a strong oxidizer. Peroxides are regularly produced naturally by a woman's body. The Prolene hernia mesh is not intended to be placed in vagina, and the TVT-O mesh contains approximately 1,000 times more plastic material than a Prolene suture, so the clinical effects of oxidization would be markedly different between a suture and the TVT-O mesh.

This warning in the Prolene MSDS should have triggered an investigation into the effects that the naturally occurring oxidizers in the vaginal would have on the TVT-O mesh prior to Ethicon's marketing of the device, particularly with regard to oxidation and degradation of the mesh, as well as inflammation caused the presence of these naturally occurring substances in a woman's vagina. At the very least, Ethicon should have passed this warning along to surgeons and patients using the TVT-O mesh so they could make an informed choice about whether or not to use the device. However, no such warning regarding the TVT-O mesh's incompatibility with strong oxidizers has been communicated in the IFU, and Ethicon never did studies specifically

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<sup>94</sup> Sunoco MSDS, 2003, 2005, 2009.

examining the clinical effect of these natural oxidizers on the TVT-O mesh. It is my opinion to a reasonable degree of medical certainty that Ethicon should have tested the clinical effects of the vaginal chemistry on the polypropylene used in the mesh and warned physicians about this incompatibility for use of the mesh in the vagina. Moreover, Ethicon should have informed physicians (and therefore patients) that the MSDS for its polypropylene noted a risk of carcinogenicity with the use of the plastic.

**D. Ethicon Failed to Disclose and/or downplayed Adverse Risks, Complications and Product Information in its Instructions for Use (“IFU”) for the TVT-O.**

Ethicon’s Instructions for Use (“IFU”) fails to disclose important safety and risk information to physicians thereby compromising the ability for all levels of surgeons to adequately and appropriately consent their patients prior to the implantation of the TVT-O device. The IFU serves as the main modality for information regarding surgery. The IFU is the one document that Ethicon knew all surgeons see prior to the implantation of the TVT-O device.<sup>95</sup> In addition, according to Ethicon’s Medical Director Piet Hinoul, physicians should be allowed to rely on the safety information in the IFU standing alone.<sup>96</sup> For this reason and according to Ethicon’s own Regulatory and Medical Affairs, all risks associated with a medical device must be included in the products’ IFU.<sup>97</sup> This is true so that all physicians know the safety and risk information known to a company and related to a specific product. In this case, the IFU for the TVT-O only lists the following information in its Adverse Risks Section for the TVT-O:

Adverse Reactions

\* Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.

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<sup>95</sup> Deposition of Dr. Richard Isenberg November 6, 2013 566:4-8

<sup>96</sup> Deposition of Dr. Piet Hinoul, January 14, 2014, 1207:18-1208:11

<sup>97</sup> Deposition of Catherine Beath, July 12, 2012, 592:7-11, Deposition of Dr. Marty Weisberg, August 9, 2013, 959:19-960:15

\* Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.

\* As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.

\* Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

The IFU for the TVT-O fails to disclose numerous adverse risks, safety information and warnings that are associated with the product, including, among others, the following: Death, pain, chronic pelvic pain, permanent dyspareunia, permanent sexual dysfunction, injury and pain to partner during sexual intercourse, negative impact on sexual function, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, surgical interventions, development of worsening incontinence and urinary dysfunction. My review of internal documents and the depositions of Ethicon employees reveals that Ethicon was aware of these risks before or at the time the TVT-O was first marketed and sold.<sup>98</sup>

Additionally, Ethicon not only failed to disclose certain defects related to the product in the IFU, they downplayed several of the actual defects. In the TVT-O IFU, Ethicon stated, “Transient leg pain lasting 24-48 hours may occur and can usually be managed with mild analgesics.” However, this warning is inconsistent with data available to Ethicon showing that the pain frequently extended beyond 48 hours and was often chronic. Additionally, defects related to the mesh that Ethicon failed to disclose in its IFU are as follows: roping, curling, fraying, particle loss, degradation, contraction and shrinkage, chronic foreign body reaction and decreased pore size. Ethicon also failed to disclose risks and information related to cytotoxicity and the MSDS discussed above.

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<sup>98</sup> Deposition of Piet Hinoul, June 27, 2013 552:2-9; Deposition of Catherine Beath, July 12, 2013; 608:13-20

Ethicon also failed to include warnings in its IFU related to the increased risk of mesh extrusion in women with prior vaginal surgeries, vaginal atrophy, vaginal injury, pre-existing pelvic pain disorders, immune-compromised and post-operative infection.<sup>99</sup> In addition, Ethicon failed to inform physicians that the TVT-O procedure performed under general anesthesia increases the risk of urinary retention, erosions and failure of the surgery. All of the above risks, safety and warning information was known to Ethicon prior to or around the time that the TVT-O was first marketed. Finally, Ethicon did not tell physicians that the TVT-O device would not work as well in smokers, young athletic women, older women or obese patients.<sup>100</sup> The failure to include this information deprived physicians of the information and prevented them from truly and fully being able to consent their patients prior implanting TVT-O devices or allow physicians to properly treat women with mesh complications.

Ethicon also downplays and misrepresents significant information in its IFU related to certain mesh properties. Despite the significant amount of data regarding mesh-related inflammatory response, the TVT-O IFU claims that implantation of Gynecare TVT-O mesh “elicits a minimal inflammatory reaction,” which is “transient”. This is not true as the inflammatory response is chronic according to my clinical experience with the mesh and the testimony of Ethicon Medical Directors David Robinson and Piet Hinoul and is extensively documented in Ethicon documents.<sup>101</sup>

In addition, Ethicon states in its IFU that the mesh is not subject to degradation, which is also inconsistent with Ethicon internal studies and documents and scientific studies examining mesh degradation. In short, Ethicon not only failed to disclose certain risks associated with the

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<sup>99</sup> Deposition of Rick Isenberg, November 6, 2013 582:17-583:1, ETH.MESH.00159634 at 00159697; ETH.MESH.00203456.

<sup>100</sup> ETH.MESH.00640394, Deposition of Aaron Kirkemo, January 7, 2014, 556:4-19; 556:24-557:1; 557:5-558:21

<sup>101</sup> Deposition of Dr. David Robinson, September 11, 2013, 1087:7-1089:15; Deposition of Dr. Piet Hinoul, January 14, 2014, 1192:4-1199:12; ETH.MESH.02340504 TVT IFU; ETH.MESH.00339437-442 “5 Years of Proven Performance” Feb 2002

product, it downplayed or inaccurately portrayed issues related to the mesh in the IFU. Ethicon prevented physicians from being able to have an appropriate and accurate informed consent discussion with their patients by concealing and misrepresenting this type of information. As a result, numerous patients have suffered injuries from the TVT-O device that were not disclosed to them as potential adverse risks related to the TVT-O.

Interestingly, in May 2015, Ethicon issued a new IFU for the TVT-O which adds numerous new risks and warnings for the first time, including but not limited to acute and/or chronic pain, dyspareunia to patients and partners that may not resolve and that one or more revision surgeries maybe be necessary to treat adverse reactions.<sup>102</sup> As stated above, Ethicon had knowledge of these risks prior to the time the TVT-O was first marketed or sold.

#### **E. Ethicon Failed To Conduct Appropriate Studies Related to the TVT-O**

Ethicon has never conducted a long-term randomized controlled trial with safety as a primary endpoint.<sup>103</sup> There are also very few studies which have actually studied chronic, long-term pain with the TVT or TVT-O.<sup>104</sup> In addition, to my knowledge, with respect to studies performed by persons outside of Ethicon, very few are long term randomized controlled studies and none include a primary endpoint of safety.<sup>105</sup> There have also been recent studies that suggest that the studies assessing risks of synthetic mid-urethral slings to date are poor and that long term data or evidence lags behind shorter-term studies.<sup>106</sup>

Ethicon routinely relies and promotes its TVT-O product based on long-term data that originates from the original DeLeval data and studies. However, these studies lack significant

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<sup>102</sup> TVT-O IFU, May, 2015

<sup>103</sup> Trial Testimony of Piet Hinoul in Linda Batiste Trial, 3-27-14 pm 57:9-12, 57:9-12

<sup>104</sup> Deposition of Dr. David Robinson, September 11, 2013, 978:7-14

<sup>105</sup> Deposition of David Robinson, 977:2-18

<sup>106</sup> Ford, et. al. Mid-urethral sling operations for stress urinary incontinence in women (review). The Cochrane Library, DOI: 10-1002/14651858.CD006375.pub3 (2015); Blaivas, et. al. Safety considerations for synthetic sling surgery. Nat. Rev. Urol. 18 August 2015, e-publication ahead of print.

data and fail to consider or inquire about many safety risks on the original patient cohort. In addition, Ethicon knew the DeLeval studies were uncontrolled, used different prototype devices and that the he had conducted his studies in violation of numerous criminal and civil laws.<sup>107</sup> The DeLeval data is also biased in that Dr. DeLeval had financial incentives to obtain certain results with his studies and received numerous payments, consulting agreements and royalties related to the TVT-O and his involvement with Ethicon.<sup>108</sup>

**F. Ethicon Failed to consider numerous known risks and hazards of the TVT-O in its design process.**

As part of its design process, Ethicon is required to look at the potential risks of the implant.<sup>109</sup> According to Ethicon's Former Medical Director, there is a very formal process related to FMEAs, failure modes and risk analysis in determining different ways that things go wrong.<sup>110</sup> In making these determinations about risks, Ethicon relies on medical expertise from urologist like me to project what potential harms might result based on experience and literature.<sup>111</sup> According to Ethicon, a risk assessment is required to take into account all of the potential harms a product can cause once implanted.<sup>112</sup>

I have reviewed the relevant risk assessment documents created as part of the design of the mechanical-cut TVT, including the Preventia risk analysis performed by Medscand AB in 2000 and the updated Risk Assessment done in 2002.<sup>113</sup> Additionally, I have reviewed the relevant risk assessment documents created as part of the design of the TVT-O.<sup>114</sup> These risk assessments leave out or do not take into account numerous risks and complications related to

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<sup>107</sup> ETH.MESH.03934952

<sup>108</sup> ETH.MESH.15955249; ETH.MESH.15363068; ETH.MESH.12002262

<sup>109</sup> Deposition of Dr. Aaron Kirkemo, January 6, 2014, 36:15-38:16

<sup>110</sup> Deposition of Dr. Aaron Kirkemo, January 6, 2014, 36:15-38:16

<sup>111</sup> Deposition of Dr. Aaron Kirkemo, January 6, 2014, 36:15-38:16

<sup>112</sup> Deposition of Scott Ciarocca, March 29, 2012, 97:23-98:21

<sup>113</sup> ETH.MESH.01317508

<sup>114</sup> ETH.MESH.00259473 (TVT-O DDSA)

the TVT-O, including roping, curling, deforming, fraying, particle loss, degradation, contraction and shrinkage, chronic foreign body reaction and decreased pore size due to its heavyweight and/or the fact that the device is impossible or difficult to remove. Based on testimony and internal documents I have reviewed and discussed above, Ethicon had knowledge of these risks at the time the TVT-O was launched.<sup>115</sup> As a result, Ethicon should have taken these into account during the design of the TVT-O and should have designed out these defects or warned about them. Because Ethicon failed to do so, the risks of the TVT-O are too great, and outweigh the benefits of the product.

For the reasons set forth above, the old construction mesh as used in the TVT-O device should not be used in the pelvic floor when implanted in this manner. These design defects of the mesh and the TVT-O lead to long term complications, pain, acute and chronic pelvic pain, vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, negative impact on sexual function, the possibility of multiple pelvic erosions that can occur throughout one's lifetime, vaginal scarring, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, need for multiple surgical interventions, development of worsening incontinence and urinary dysfunction including urinary urgency, urinary urge incontinence, urinary retention, suprapubic pain, suprapubic numbness, pain with lifting, pain with ambulation, and pain with sitting.

## **V. Exhibits**

My current curriculum vitae is attached as Exhibit "A"

All materials that have been available to me to consider in support of my finding and opinions are included above and listed below in Exhibit "B".

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<sup>115</sup> Deposition of Piet Hinoul, June 27, 2013 552:2-9; Deposition of Catherine Beath, July 12, 2013; 608:13-20

## **VI. Recent Testimony**

I have testified as an expert at the following trial:

*Coloplast A/S v. Generical Medical Devices*; United States District Court – Western District of Washington at Tacoma Case No. C10-227BHS

*Linda Gross et al. v. Gynecare, et al.*; Superior Court of New Jersey Law Division – Middlesex County Case No. MID-L-9131-08

*Diane Bellew v. Ethicon et al.*; United States District Court, Southern District of West Virginia Case No. 2:12-cv-22473

*Janice L. St. Cyr v. C.R. Bard, Inc. et al.*; United States District Court, Southern District of West Virginia Case No. 2:14-cv-02313

*Kathleen Stanbrough v. C.R. Bard, Inc. et al.*; United States District Court, Southern District of West Virginia Case No. 2:14-cv-06937

*Sheila Sutton v. C.R. Bard, Inc. et al.*; United States District Court, Southern District of West Virginia Case No. 2:14-cv-00105

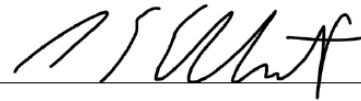
*Pamela Ailey v Cook Medical, Inc., et al.*; United States District Court, Southern District of West Virginia Case No. 2:13-CV-20496

## **VII. Compensation**

I am compensated for investigation, study and consultation in the case at the rate of \$700.00 per hour.

February 1, 2016

DATE



DANIEL ELLIOTT, M.D.



**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<p><b>IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b></p> <p><b>THIS DOCUMENT RELATES TO WAVE 1</b></p>	<p><b>Master File No. 2:12-MD-02327</b></p> <p><b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b></p>
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**RULE 26 EXPERT REPORT OF DANIEL ELLIOTT, M.D.**

**I. Background and Qualifications**

I am an Associate Professor of Urology at Mayo Graduate School of Medicine in Rochester, Minnesota. I received an M.D. in 1993 from Loma Linda University School of Medicine in Loma Linda, California. Following graduation from medical school, I completed my surgical residency in Urology at the Mayo Graduate School of Medicine at the Mayo Clinic in 1999. I completed a one-year advanced surgical fellowship at Baylor College of Medicine in Houston, Texas, in Neurourology, Urodynamics, and Voiding Dysfunction. I then re-joined the faculty at the Mayo Clinic, where I have spent the last 15 years specializing in treatment for pelvic organ prolapse and urinary incontinence in women, as well as urinary incontinence in men. I have published over 60 peer-reviewed articles and given more than 100 hundred lectures, many of which relate to urinary incontinence and pelvic organ prolapse. A Mayo Clinic colleague and I were the first to perform robotic sacrocolpopexy surgery for the treatment of high-grade prolapse and the first to publish extensively on the subject. I have also published multiple scientific manuscripts concerning polypropylene meshes in the animal model. I am a frequent invited lecturer at medical and surgical conferences addressing pelvic organ prolapse

and stress urinary incontinence and their evaluation, treatments, surgical options, and management of complications. I recently passed the subspecialty credentialing process for Female Pelvic Medicine and Reconstructive Surgery, established by the combined boards of the American Board of Urology and the American Board of Obstetrics and Gynecology. Attached as Exhibit “A” to this report is a copy of my current curriculum vitae, which includes an up-to-date list of my publications, presentations, awards, and other academic activities, as well as my fee schedule. My recent trial testimony is listed in Exhibit “B.”

## **II. Bases of Opinions**

I have been asked to provide opinions regarding the subject of female stress urinary incontinence, its evaluation, treatments, surgical options and management of complications as well as to address the actions of Ethicon, Inc., Ethicon Women’s Health and Urology, a Division of Ethicon, Inc., Gynecare and Johnson & Johnson (collectively referred to as Ethicon). The focus of my investigation for this report is on the TVT-Secur System (“TVT-S”) and, specifically, the characteristics of the product that make it defective or, in other words, that make the risks to the patient outweigh the benefits to the patients. My opinions are based on my personal knowledge, experience, and my investigation in this case. All of my opinions, and the bases of those opinions, are true and correct to the best of my knowledge and belief, including those related to scientific and medical issues, which I believe to be true and correct to a reasonable degree of scientific and medical certainty. I do, however, reserve the right to supplement this report and my opinions in light of any additional material or information provided to me, including any reports submitted and/or any other discovery that is taken in this case. Furthermore, if called to testify, I would plan to use various demonstrative exhibits,

animations, video recordings, and/or anatomic models to show the relevant anatomy and surgical procedures and to describe my opinions as set forth in this report.

My opinions and conclusions regarding the TVT-S, its surgical procedure, its impact on patients and surgical colleagues, as covered throughout this report, have not been derived in isolation or from solitary data and opinion; rather, my report has been formed and influenced by multiple sources, briefly summarized as follows: my independent clinical and laboratory mesh-specific research, including clinical manuscripts pertaining to female stress urinary incontinence (“SUI”), female pelvic organ prolapse (“POP”), including mesh-specific complications; animal laboratory studies regarding the effects of polypropylene mesh and host foreign body response and inflammatory response; advanced surgical fellowship training in Voiding Dysfunction and Neurourology, which is above and beyond the normal six-year urologic surgical training; my personal surgical, clinical, and research experience implanting Prolene mesh slings; my personal surgical, clinical, and research experience as a Female Pelvic Medicine and Reconstructive surgical specialist at a high-volume tertiary center managing highly complicated SUI patients and mesh-related complications, including medical and surgical revisions and removal and treatment of synthetic mesh slings, including complications caused by the TVT-S device; my attendance and participation at national and international Urological and Gynecological surgical meetings, including but not limited to the International Pelvic Pain Society, International Continence Society, Society of Female Urology and Urodynamics, American Urologic Association, Canadian Urological Association, Mayo Clinic Urology Review, UCLA State of the Art Urology, European Urological Association Subsection of Female Urology and Subsection of Reconstructive Urology. I have prepared and given lectures at national and international meeting specifically focused on the complexities of treating female SUI and the management of

complications associated with such treatments, including but not limited to the International Continence Society meeting, Society of Female Urology and Urodynamics meeting, American Urologic Association meeting, Canadian Urological Association meeting, UCLA State of the Art Urology meeting, and European Urological Association Subsection of Female Urology and Reconstructive Urology meeting. I have had personal interactions and discussions with national and international urologic, gynecologic, urogynecologic, and general surgery colleagues regarding the management of SUI in women, manifestation of mesh-specific complications, and the treatment of mesh-specific complications. As part of my interest in being as educated and as up-to-date and accurate as possible, I have reviewed the readily available medical literature pertaining to the treatment of SUI and the management of its complications from sources including but not limited to medical journals, the United States National Library of Medicine, and the National Institute of Health.

I am a surgical journal editor and/or reviewer for 14 urologic and/or gynecologic journals (please see Curriculum Vitae for complete listing of journals) and was named Best Reviewer in Female Urology/Incontinence/Neurourology for two consecutive years (2012-2013) for the Journal of Urology. This is the highest honor awarded by the Editor of the Journal of Urology for excellence in manuscript review and preparation.

I have also performed a systematic review of internal Ethicon documents as they pertain to surgical mesh, TVT-S, the TVT-S procedure, expected SUI surgical results, expected SUI complications and rates of SUI complications, and marketing strategies designed for my surgical colleagues in urology, gynecology and urogynecology, as well as for potential SUI patients. I have also reviewed the testimony of Ethicon employees. All materials I reviewed or relied on in

support of my findings and opinions are included throughout this report and/or listed in Exhibit “C.”

### **III. Summary of Opinions**

#### ***A. Background on SUI and Treatments***

1. Stress Urinary Incontinence
2. Alternative/Traditional SUI Treatment Options
  - a. *Non-surgical*
  - b. *Surgical*

#### ***B. The Polypropylene Mesh in the TVT-S Should Not Be Used in the Pelvic Floor Due to Known Complications and Hazards***

1. Polypropylene mesh in the TVT-S is not inert and degrades
2. The MSDS for the Prolene mesh states not to use with strong oxidizers like peroxides, which can be abundantly found in the vagina
3. The TVT-S mesh is heavy with small pores, causing increased tissue response, chronic inflammatory response, contraction and shrinkage of the mesh, fibrotic bridging and scar plate formation
4. Ethicon’s Prolene mesh tested positive for cytotoxicity

#### ***C. The TVT-S Should Not Be Used in the Pelvic Floor Due to its Defective Design***

1. The TVT-S mesh is laser cut, resulting in a stiffer product and higher incidence of complications
2. The TVT-S design is flawed because there is no way to properly tension the device
3. The TVT-S is defectively designed in its insertion instruments and technique
4. Ethicon had several preferred alternatives to the TVT-S available

#### ***D. Ethicon Failed to Disclose and/or Downplayed Adverse Risks, Complications, and Product Information in its Instructions for Use (“IFU”) and Patient Brochures***

#### ***E. Ethicon Failed to Provide Adequate Training for Surgeons Using the TVT-S***

#### **IV. Expert Opinions**

##### ***A. Background on SUI and Treatments***

###### **1. Stress Urinary Incontinence**

Female stress urinary incontinence (“SUI”) is a relatively common condition in which a woman leaks urine when her body experiences an increase in abdominal pressure, which in turn increases the pressure on the bladder. The abdominal pressure (A.K.A. “stress”) is caused by a wide variety of activities including coughing, laughing, sneezing, jumping, bending over, picking something up, running, or any other sudden movement that increases pressure on the bladder.

In a woman, the urine leakage often results from weakening of the muscles that surround the urethra and/or a lack of fascial support for the urethra. The fascia below the urethra serves as a sort of net to prevent the urethra from falling. SUI is much more common in women than in men, largely because of pregnancy, childbirth, menopause and hysterectomies, among other factors. Each of these conditions cause physical changes in the fascia used to support the urethra, which in turn results or contributes to SUI. There are multiple fascias, or tissues, that support the urethra, including fascia located in the area of the pelvic floor and endopelvic fascia. In a woman with SUI, these fascia fail to provide sufficient support for the urethra, allowing the urethra to move downward when there is a sudden increase in pressure, such as that caused by a cough or a sneeze. When this happens, urine leaks out of the urethra. Some SUI can also be linked to intrinsic sphincter deficiency (“ISD”), a condition in which the urinary sphincter is weakened.

SUI can have very serious effects on a woman’s physical and mental health. It is not uncommon for women with SUI to stop participating in activities they once enjoyed, such as sports and other recreational activities, or to experience mental illness such as depression.

## 2. Alternative/Traditional SUI Treatment Options

### *a. Non-surgical*

SUI presents in 15% to 35% of women.<sup>1</sup> Although some surgical treatments are typically safe and highly effective, many patients wish to avoid surgery for a variety of reasons. Regardless of the patient's willingness to commit to surgery, in most cases, it is recommended that non-surgical options be implemented first.<sup>2</sup>

#### *Behavior modification & Pelvic Floor Therapy & Exercises*

Simple lifestyle or behavioral modifications such as weight loss and/or avoidance of dietary irritants like caffeine and nicotine are often the first line of treatment. In many cases those options may be the only treatment necessary. Additionally, pelvic floor muscle exercises (Kegel exercises) are used to strengthen the muscles surrounding the urethra so that urine is less likely to leak. These therapies require time, effort, and commitment, but they do not have side effects and are often very effective.

Alternatively, pelvic floor electrical stimulation combined with biofeedback may prove useful. Pelvic floor electrical stimulation utilizes electrical current to strengthen the pelvic floor and improve its function. Biofeedback is a treatment regimen performed under the care of a specialist and/or physical therapist. It is a safe and effective method of increasing pelvic floor strength and has a role in helping women with mild stress incontinence. Biofeedback attempts to retrain patients on how to more appropriately use their pelvic floor muscles, thereby improving

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<sup>1</sup> Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, van Kerrebroeck P, Victor A, Wein A, Standardisation Sub-committee of the International Continence Society Neurourol Urodyn. 2002; 21(2):167-78. Milsom I, Altman D, Lapitan MC, Nelson R, Sillen U, Thom D. Epidemiology of urinary (UI) and Faecal (FI) Incontinence and Pelvic Organ Prolapse. In: Abrams P, Cardozo L, Khoury S, Wein A, editors. Incontinence; 4th International Consultation on Incontinence; Paris: Health Publication Ltd; 2009. pp. 35–111.

<sup>2</sup> Hay-Smith J, Berghmans B, Burgio K, et al. Adult Conservative Management. In: Abrams P, Cardozo L, Khoury S, Wein A, editors. Incontinence; 4th International Consultation on Incontinence; Paris: Health Publication Ltd; 2009. pp. 1025–1120.

their urine control. Consequently, the patient becomes more aware of her pelvic muscles and is better able to identify and use them.

#### *Medication*

There are several medications that have been studied for the potential treatment of SUI (Topical Estrogen,  $\alpha$ -Adrenergic Agonists, Imipramine, Duloxetine,  $\beta$ -Adrenergic Antagonists, and  $\beta$ -Adrenergic Agonists). However, to date their benefit is minimal for SUI and is essentially limited to possibly benefiting overactive bladder.

#### *Pessaries*

Pessaries have been used for thousands of years to treat POP and SUI and, prior to the advent of successful surgical options, pessaries were essentially the only viable treatment for POP and SUI. Specifically, “continence pessaries” represent an alternative or complementary non-surgical approach to the treatment of SUI. These devices work by providing a platform against which the urethra can compress during strenuous activity such as lifting or coughing. There are several studies describing the effectiveness of pessaries for treatment of SUI, but most of these studies are based on small samples of participants with short-term follow-up, which make the results questionable. Ultimately, however, due to inherent limitations of effectiveness complications such as vaginal pain, discharge, and odor, and the necessity of routine medical care, most patients with SUI discontinue using the pessary at some point.

#### *b. Surgical*

Surgeons have spent hundreds of years trying to develop successful treatments for SUI. Over time, several successful surgical techniques have been devised, but all of the treatments have the common component of reestablishing support for the urethra that has been weakened and damaged by childbirth, hysterectomy, obesity, and/or age.



*Marshall-Marchetti-Krantz & Burch Colposuspension*

In the 1940's, the Marshall-Marchetti-Krantz ("MMK") procedure was developed. The MMK procedure is a surgery in which the surgeon secures the neck of the bladder—i.e., where the bladder meets the urethra—to the pubic bone with a series of sutures. The Burch colposuspension procedure was developed shortly after the MMK procedure. The Burch procedure is successful in treating urinary incontinence with success rates equivalent to mid-urethral synthetic slings. Although the Burch procedure takes longer than a procedure to implant a synthetic mid-urethral sling, the long-term complications with Burch, particularly relating to chronic pain and dyspareunia, are minimal when compared to the complications arising from mid-urethral synthetic slings.

*Pubovaginal Slings (Autologous/Cadaveric)*

In the 1980's, a major advancement occurred with the introduction of a procedure known as the pubovaginal sling (PVS). The PVS procedure uses harvested tissue from the tough abdominal wall, called abdominal fascia. That tissue is then implanted in the shape of a hammock-like sling around the neck of the bladder and up to the abdominal wall. Since the fascial tissue comes from the patient herself, it is called "autologous," meaning tissue that comes from the same individual. The procedure rapidly rivaled the Burch colposuspension as the "gold standard" for the treatment of SUI in women.

With the advent of biologic and synthetic mesh slings, the number of traditional PVS procedures initially decreased. However, with the increasing awareness among surgeons and patients regarding the complications of vaginal synthetic mesh (including but not limited to permanent dyspareunia, life-altering pain, chronic sexual dysfunction, lifetime erosion risk, and others listed throughout this report), the PVS procedure has seen a significant resurgence. In

some regions and practices around the nation, the PVS has become the mainstay of therapy. In my own practice at a major tertiary referral medical center, I have abandoned essentially all synthetic mesh sling implantation due primarily to those complications mentioned above.

### *Synthetic Mesh in General Surgery*

Abdominal and thoracic wall weaknesses (hernias) develop due to conditions such as birth defects, surgical complications, and radiation effects. Traditional hernia repair surgery evolved using sutures (stitches) to bring native tissue together. However, due to the inherent weaknesses of the tissues, failure was common and frequently resulted in significant pain and suffering for the patient. As a result, surgical meshes for hernia repairs were introduced in the 1950's. Since then, academic presentations, surgical reports, and journal manuscripts have described mesh-related complications such as chronic pain, abdominal wall rigidity, mesh contraction, infection, fistula formation, chronic inflammatory process, and weakness recurrence.<sup>3</sup>

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<sup>3</sup> Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. *Expert Rev Med Devices*. 2005 Jan; 2(1):103-17. Agresta F, Baldazzi G, Ciardo et al: Lightweight partially absorbable monofilament mesh (polypropylene/poliglecaprone for TAPP inguinal hernia repair. *Surg Laparosc Endosc Percutan tech* 2007, 17; 91- 94. Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. *Hernia* (1997)1:15-21. Bellon J, Honduvilla N, Jurado F et al: In vitro interaction of bacteria with polypropylene/ePTFE prostheses. *Biomaterials*. 2001 Jul; 22(14):2021-4. Bouikerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. *European J. Obstet & Gynecol and Repro Bio* 134: (2007)262-267. Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. *European Journal of Surgery* Volume 164, Issue 12, pages 965–969, December 1998. Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. *Eur J Surg*. 1999 Jul; 165(7):665-73. Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. *J. Surgical Research* 103, 208-214 (2002). Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene- mesh modifications for abdominal wall repair. *Biomaterials*. 1998 Dec; 19(24):2235-46. 13 Krause H, Galloway S, Khoo S et al: Biocompatible properties of surgical mesh using an animal model. *Aust N Z J Obstet Gynaecol*. 2006 Feb; 46(1):42-5. Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. *Int Urogynecol J*. 2011 Jan; 22(1):47-52. Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. *American Journal of Surgery* Vol 193, Issue 4, April 2007, p538-542. Cappelletti M, Attolini G, Cangioni G, et al. The use of mesh in abdominal wall defects. *Minerva Chir*. 1997 Oct; 52(10):1169-76. Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long- term implantation in humans. [ABSTRACT] *Chirugr* 2000; 71:43-51. Seker D, Kulacoglu H. Long-term complications of mesh repairs for abdominal wall hernias. *J Long Term Eff Med Implants*. 2011; 21(3):205-18. Cobb W, Burns J, Peindl R et al: Textile analysis of heavyweight, mid-weight, and lightweight polypropylene mesh in a porcine ventral hernia model. *J Surgical Research* 136, 1-7 (2006). Pandit A, Henry J. Design of surgical meshes - an engineering perspective. *Technol Health Care*. 2004; 12(1):51- 65. Pierce L, Grunlan M, Hou Y et al: Biomechanical properties of synthetic

An abundance of evidence in medical literature and basic scientific data has been accumulated over the past two decades and indicates a strong and direct relationship between postoperative mesh complications and mesh design.<sup>4</sup> Reducing mesh-related complications demands a thorough understanding and knowledge of the chemical, physical, and synthetic characteristics of meshes and how they react inside the human body. At this point, there is a scientific consensus that synthetic meshes that are low-weight, large-pore, high porosity, monofilament, and capable of maintaining their elasticity under load have better results with fewer complications. Of all mesh characteristics, mesh stiffness, porosity, and pore size are of critical importance.

#### *Synthetic Mesh Use in Pelvic Floor*

The TVT-S was cleared for use based on its similarity to predecessor devices, like Ethicon's TVT-Retropubic and TVT-Obturator. During the TVT-R's Food and Drug Administration submission process in the late 1990's, Ethicon used the ProteGen sling as its predicate device. Introduced in April 1997 as a treatment for female SUI, the ProteGen sling was a synthetic polymer (polyester) mesh sling implant—not a polypropylene mesh as in the TVT line of products, including the TVT-S. Surgeons implanted the ProteGen polyester sling

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and biologic graft materials following long-term implantation in the rabbit abdomen and vagina. Am J Obstet Gynecol. 2009 May; 200(5):549.e1-8. Costello C, Bachman M, Grand, S, et al. Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient. Surg Innov. 2007Sep; 14(3):168-76.

<sup>4</sup> ETH.MESH.00869977; ETH.MESH.02589033; Robinson deposition 7-13, pg. 126-30; Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan; 2(1):103-17. Agresta, F, Baldazzi G, Ciardo et al: Lightweight partially absorbable monofilament mesh (polypropylene/poliglecaprone for TAPP inguinal hernia repair. Surg Laparosc Endosc Percutan Tech 2007, 17; 91-94. Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia (1997) 1:15-21. Bellon J, Honduvilla N, Jurado F et al: In vitro interaction of bacteria with polypropylene/ePTFE prostheses. Biomaterials. 2001 Jul; 22(14):2021-4. Bouikerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. European J. Obstet & Gynecol and Repro Bio 134: (2007)262-267. Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998. Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul; 165(7):665-73. Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002).

underneath the urethra to provide support and to reduce SUI. Unfortunately, nearly immediately following ProtoGen's launch, a large number of patients began experiencing severe complications like mesh erosion through the vaginal wall, vaginal infections, vaginal discharge, vaginal bleeding, foul odor, and dyspareunia. In January 1999, Boston Scientific Corporation, ProtoGen's manufacturer, recalled the product due to the unusually high number of complications. In the December 1999 edition of *The Journal of Urology*, a group of respected urologists from across the United States reported their findings on those complications, including a high rate of tissue erosion and urethral erosion.

In November 1998, just months before the ProtoGen recall, Ethicon brought its Tension Free Vaginal Tape (TVT) System to the US market as part of its Gynecare line. The TVT was designed as a pubourethral sling for treatment of female SUI. The device is made from polypropylene mesh (sometimes referred to by the trade name PROLENE). Despite the ProtoGen recall and the two decades worth of literature on the complications resulting from polypropylene mesh implants, the TVT remains on the market today. In fact, Ethicon has expanded the TVT line to include the TVT-O, which incorporates an obturator device to implant the mesh via an "inside-out" approach, and the TVT-S device, which is the primary focus of this report.

Ethicon received FDA approval for the TVT-S device, a single incision sling ("SIS") sometimes referred to as a "mini-sling," in 2005. The sling was composed of approximately 1.1cm x 8.0cm of polypropylene mesh (Prolene) and could be inserted via either the "Hammock approach" or the "U approach." The TVT-S device was removed from the market in 2012, after the FDA requested that Ethicon conduct postmarket surveillance studies. No such studies were performed, and the TVT-S remains off the market to this day.

***B. The Polypropylene Mesh in the TVT-S Should Not Be Used in the Pelvic Floor Due to Known Complications and Hazards***

Because of the defective characteristics of the TVT-S, as discussed below and throughout this report, Ethicon repeatedly fell below the standard of care in producing and marketing its device. The laser cut mesh used in the TVT-S device should not be used in the pelvic floor, because the risks of the device far outweigh the benefits of the device. The inadequacies of the Prolene mesh and the TVT-S device lead to long term complications, including but not limited to acute and chronic pelvic pain, acute and chronic vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, sexual dysfunction, chronic infections, abscess formation, permanent nerve damage, defecatory dysfunction, chronic foreign body reaction, lifelong risk of erosion and extrusion, severe vaginal scarring, inability to remove the device, the need for multiple surgical interventions that carry with them significant risks of morbidity, the development of worsening incontinence and urinary dysfunction, including urinary urgency, urinary urge incontinence, and urinary retention. As such, the TVT-S device is not suitable as a permanent implant.

1. The mesh in the TVT-S is not inert and degrades

As polypropylene has been used in surgery for over 50 years as a suture material, Prolene mesh, like the kind used in the TVT-S, was marketed by Ethicon as inert. However, many published studies and internal Ethicon documents show that the mesh is not inert and does in fact degrade.<sup>5</sup> In 1987, for example, Ethicon tested samples of explanted Prolene mesh made from

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<sup>5</sup> ETH. MESH.08315783; ETH.MESH.02589033; Robinson Deposition 7-13, p120, 129-130; Hinoul Deposition 4-5, p165-170; Kirkemo Deposition 4-18, p138; 84 Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul;165(7):665-73. Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002). Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998.; Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Biomaterials. 1998 Dec;19(24):2235-46.;

the same material as the TVT-S mesh.<sup>6</sup> After 8 years of implantation, the testing showed that the mesh was severely cracked. In 1992, Ethicon completed a study where Prolene sutures were implanted in beagle dogs for up to seven years. These sutures were removed from the dogs and examined by Ethicon's own scientists, who found surface degradation in many of the samples after 7 years of implantation.<sup>7</sup> Ethicon scientist and corporate spokesperson, Thomas Barbolt, agreed that surface degradation can occur with Prolene mesh, and that this fact was confirmed by the Ethicon studies.<sup>8</sup>

Further evidence that polypropylene mesh degrades over time was provided in 1998 by the publication of the Mary article, who studied the phenomenon of mesh degradation, and concluded the process of polypropylene cooling, where the polypropylene strand cools first on the inside and then on the outside can make the strand more susceptible to degradation on the outside.<sup>9</sup> In 2007, Costello et al., reported that polypropylene is more susceptible to degradation due to oxidation caused by inflammatory response.<sup>10</sup> Using Scanning Electron Microscopy (SEM), degradation could be seen in polypropylene in the form of cracks and peeling.

Dr. Donald Ostergard, urogynecologist and founder of AUGS, created a presentation titled "Polypropylene is Not Inert in the Human Body" in which he described degradation of in vivo

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Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. [ABSTRACT] Chirugr 2000;71:43-51.; Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan;2(1):103-17. Clave A, Yahi H, Hammou J, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 patients. Int Urogynecol J. 2010 Mar;21(3):261-70. Klinge et al The Ideal Mesh Klosterhalfen et al: Retrieval study at 623 human mesh explants made of polypropylene.

<sup>6</sup> ETH.MESH.12831407

<sup>7</sup> ETH.MESH.05453719

<sup>8</sup> Barbolt deposition, 1-14, p409, 516-517

<sup>9</sup> Mary C, Marios Y, King MW, et al. Comparison of their in vivo behavior of polyvinylidene fluoride and polypropylene sutures used in vascular surgery. ASAIO Journal 44, 1998, 199-206.

<sup>10</sup> Costello C, Bachman M, Grand S, et al. Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient. Surg Innov. 2007 Sep; 14(3):168-76.

polypropylene.<sup>11</sup> Dr. Ostergard concluded that Prolene mesh degradation occurs by oxidation. He further concluded that a large surface area, such a piece of surgical mesh, in contrast to a suture, incites more inflammation and results in more oxidation since more macrophages are present. These macrophages then secrete hydrogen peroxide and hypochlorous acid to oxidize the mesh, which can cause the mesh to become brittle and to crack. As discussed below, these changes cause complications to patients due to the increased inflammatory response.

In a 2010 article by Clave et al., 100 pelvic floor explants were analyzed.<sup>12</sup> Results showed that *all types of polypropylene implants exhibited degradation*. “Mesh damage included superficial degradation, which appeared as a peeling of the fiber surface, transverse cracks in the implant threads, significant cracks with disintegrated surfaces and partially detached material, and superficial or deep flaking.” The authors concluded that their research directly “contradicts” the idea that polypropylene is “an inert material.” The authors further stated that “[f]or transvaginal surgery, clinical experience indicates the use of low density, large pore implants knitted from a monofilament to facilitate tissue integration, and decrease the inflammatory response.... [N]ot all types of PP implants degraded equally.” The authors hypothesized that in vivo oxidation of polypropylene implants, “as reported in the literature,” oxidation due to free radical attack, or “septic environment and large detachments of the vaginal approach resulting in collection and bruising hematoma [supporting] both the accumulation of fatty acids and an increased risk of infection,” could contribute to degradation. It should be noted that the lead author, Henri Clave, holds an educational position for Ethicon Europe. Two other authors had ties to Sofradim and Covidien.

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<sup>11</sup> “Polypropylene is Not Inert in the Human Body” Presentation by Donald R. Ostergard

<sup>12</sup> Clave A, Yahia H, Hammou J, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 patients. *Int Urogynecol J*. 2010 Mar;21(3):261-70.



Later, in 2013, the Wood study found that polypropylene explanted from a patient showed significant oxidation of the material, and concluded that polypropylene will degrade in an oxidizing environment, such as human tissue undergoing a foreign body response.<sup>13</sup> In 2015, seven explants from “Gynemesh, TVT, TOT, SPARC and minisling” were explanted 4-7 years after implantation. Comparison of SEM images for explant samples with control pristine samples revealed extensive surface degradation and the formation of surface cracks in the samples, demonstrating that polypropylene fibers from mid-urethral slings are not inert over time.<sup>14</sup> Other authors and studies have demonstrated similar results with polypropylene in general.<sup>15</sup> Dr. Iakovlev has published numerous articles showing and explaining the degradation and surface cracking of polypropylene explants using histological and transmission electron microscopy approaches.<sup>16</sup>

The fact that polypropylene cracks and breaks inside the human body is a serious concern. As polypropylene degrades, the human body’s inflammatory response increases and intensifies. The abraded fiber surface increases the surface area of the mesh, providing multiple areas that can effectively harbor bacteria and become brittle, which lead to an increased risk of an

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<sup>13</sup> Wood, et. al. Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. *J Mater Sci*: 24:1113-1122 (2013).

<sup>14</sup> K Tzartzeva, D Lingam, M Baniyadi, M Minary-Jolandan, P Zimmern. *Neurology and Urodynamics*. 2014 33 (6), 820-822.

<sup>15</sup> Iakovlev, et al., Pathology of Explanted Transvaginal Meshes. *Intl . Science Index Vol. 8 No. 9* (2014); Martin, MK Gupta, JM Page, F Yu, JM Davidson, SA Guelcher, CL Duvall. Synthesis of a Porous, Biocompatible Tissue Engineering Scaffold Selectively Degraded by Cell-Generated Reactive Oxygen Species. *Biomaterials* 35(12):3766-76, 2014; AE Hafeman, KJ Zienkiewicz, AL Zachman, HJ Sung, LB Nanney, JM Davidson, SA Guelcher. Characterization of degradation mechanisms of biodegradable lysine-derived aliphatic polyurethanes. *Biomaterials* 32(2):419-29, 2011.

<sup>16</sup> Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. *Virchows Archiv* 2014, 463(1): 35; Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. *Virchows Archiv* 2014, 463(1):35.



enhanced and chronic inflammatory response, severe scarring, and chronic infections due to bacterial proliferation at the mesh surface.<sup>17</sup>

As stated, Ethicon knew this information decades before the launch of the TVT-S. There are Ethicon studies dating back as far as 1983, using methods nearly identical to Dr. Iakovlev's, showing in vivo degradation of the Prolene polypropylene material.<sup>18</sup> Ethicon conducted additional studies in 1985 (dog study) and in 1987 (human explant), both showing in vivo degradation and cracking of the polypropylene materials.<sup>19</sup> Eventually, Ethicon had its meshes reviewed by an outside consulting company, which found that Ethicon meshes degrade and that the process starts within days of implant.<sup>20</sup>

Remarkably, Ethicon's IFU still claims that the mesh in the TVT-S, "is not absorbed, nor is it subject to degradation or weakening by the action of enzymes."<sup>21</sup> Such a statement is reckless and knowingly false, putting patients at risk for serious complications and leaving physicians without knowledge critical to making informed decisions. It is my opinion, to a reasonable degree of medical and scientific certainty, that polypropylene degrades in the human body, causing complications including but not limited to acute and chronic pelvic pain, acute and chronic vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, sexual dysfunction, chronic infections, abscess formation, permanent nerve damage, defecatory dysfunction, chronic foreign body reaction, lifelong risk of erosion and extrusion, severe vaginal scarring, inability to remove the device, the need for multiple surgical interventions that carry with them significant risks of morbidity, the development of worsening

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<sup>17</sup> Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. *Int Urogynecol J*. 2011 Jan;22(1):47-52.

<sup>18</sup> ETH.MESH.15955438

<sup>19</sup> ETH.MESH.00004755; ETH.MESH.11336474; ETH.MESH.13334286

<sup>20</sup> ETH.MESH.07192929

<sup>21</sup> ETH.MESH.02340568

incontinence and urinary dysfunction, including urinary urgency, urinary urge incontinence, and urinary retention. Undoubtedly, Ethicon should have informed doctors of the known fact of degradation, and the company should have conducted clinical testing relating to the impact of polypropylene degradation in the pelvic floor. Such testing would have confirmed the fact that polypropylene is not suitable for permanent implantation in the human body.

2. The MSDS for the Prolene mesh states not to use with strong oxidizers like peroxides, which can be abundantly found in the vagina

The fact that polypropylene degrades in vivo is especially problematic given the naturally occurring oxidizers in the pelvic floor. Ethicon was warned in advance of the potential consequences of permanently implanting polypropylene in the female body.

The polypropylene mesh in the TVT-S is made from plastic pellets supplied by Sunoco, a petrochemical company. Included with these plastic pellets is a material safety data sheet (“MSDS”), a public document intended to provide those handling or working with the product instructions and information on how to handle the substance in a safe matter, and, more generally, intended to describe the safety (or lack thereof) of a particular product.<sup>22</sup> I have reviewed a number of data sheets for the resin used by various manufacturers to produce pelvic mesh products.

The MSDS for the TVT-S polypropylene states:

#### **INCOMPATIBILITY**

The following materials are incompatible with this product: Strong oxidizers such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite, calcium hypochlorite and permanganates. Chlorine; Nitric acid.<sup>23</sup>

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<sup>22</sup> Weisberg deposition 8-13, p909.

<sup>23</sup> ETH.MESH.02026591

Although the resin used to make the TVT-S mesh is also used in number of other Ethicon products, including Prolene hernia mesh and Prolene sutures, this warning is particularly important as it applies to the TVT-S mesh, as the TVT-S mesh is intended to be placed in the vagina, which is a ready and natural source of peroxides, a strong oxidizer. Peroxides are regularly and naturally produced by a woman's body. By contrast, the Prolene hernia mesh is not intended to be placed in vagina. Further, TVT-S mesh contains approximately 1,000 times more plastic material than a Prolene suture, so the clinical effects of oxidization would be markedly different between a suture and the TVT-S mesh.

This warning in the Prolene MSDS should have triggered an investigation into the effects of naturally occurring oxidizers on the TVT mesh prior to Ethicon's marketing of the device (and certainly prior to the TVT-S, developed years later), particularly with regard to oxidation and degradation of the mesh, as well as inflammation caused the presence of these naturally occurring substances. At the very least, Ethicon should have passed this warning along to surgeons and patients using Prolene mesh, so that they could make an informed choice about whether or not to use the device. However, no such warning regarding the TVT-S mesh's incompatibility with strong oxidizers has been communicated, and Ethicon never did studies specifically examining the clinical effect of these natural oxidizers on the TVT-S mesh. It is my opinion to a reasonable degree of medical certainty that Ethicon has failed in its duty as a reasonable medical device manufacturer by failing to include this warning in the IFU, and by failing to adequately study the clinical effects of the vagina's natural oxidizers on Prolene mesh.

Disturbingly, the MSDS also states that subcutaneous implantation of polypropylene led to local sarcomas in lab rats. The carcinogenic properties of polypropylene also should have been

disclosed to doctors, and Ethicon should have done follow-up studies relating to Prolene and cancer. No such disclosure or studies occurred.<sup>24</sup>

3. The TVT-S mesh is heavy with small pores, causing increased tissue response, chronic inflammatory response, contraction and shrinkage of the mesh, fibrotic bridging and scar plate formation

#### *Inflammation and Chronic Foreign Body Response*

As stated, the Prolene mesh used in devices like the TVT-S is the same mesh Ethicon has used for decades. Ethicon itself refers to the Prolene mesh as “old.”<sup>25</sup> Importantly, Ethicon scientists have known for more than 16 years that heavyweight, small pore meshes, like the Prolene mesh comprising the TVT-S, are associated with excessive foreign body reaction, chronic inflammation, bridging fibrosis, scar plate formation, and consequential shrinkage of the mesh.<sup>26</sup> Ethicon knew that the mesh used in the TVT-S is heavyweight and has small pores.<sup>27</sup> Ethicon also knew the need for lighter weight materials, which elicit a lower inflammatory response in the human body.<sup>28</sup>

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<sup>24</sup> Robinson deposition 9-13, p1105-1115

<sup>25</sup> ETH.MESH.10633520 -22


<sup>26</sup> ETH.MESH.05479411; Klinge U., Klosterhalfen B., Birkenhauer V., Junge K., Conze J., and Schumpelick V., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model; Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surgical Innovation. 2005; 12(1):T1-T7; Cobb, W., et al. Textile Analysis of Heavyweight, Mid-Weight, and Lightweight Polypropylene Mesh in a Porcine Ventral Hernia Model. Journal of Surgical Research 136, 1-7 (2006); Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998; 164; 965-969; Klosterhalfen, B., Junge, K., Klinge, U. The lightweight and large porous mesh concept for hernia repair. Expert Rev. Med. Devices. 2005; 2(1)

<sup>27</sup> ETH.MESH.05479411; ETH.MESH.05479535. Cobb et. al., The Argument for Lightweight Polypropylene Mesh in Hernia Repair, Deposition of Joerg Holste, July 29, 2013 40:12-15, Hellhammer Deposition, 11-13, p151.

<sup>28</sup> ETH.MESH.01203957; ETH.MESH.05479411; Trial Testimony of Piet Hinoul, *Batiste*, March 27, 2014 afternoon, p73.

### Experience with Heavyweight Meshes

- Excessive foreign body reaction
- Chronic inflammation
- Unorganized fibrocollagenous ingrowth
- Scar plate formation
- Shrinkage from bridging fibrosis
- Stiffness – abdominal wall restriction



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In fact, Ethicon developed lighter weight materials for use elsewhere in the human body, including the pelvic floor.<sup>30</sup> However, Ethicon continued to use the heavyweight, small pore Prolene mesh, originally developed in 1974 for use in hernia surgery, for its TVT-S device used for SUI.<sup>31</sup> This is true despite the fact that Ethicon knows the heavyweight, small pore meshes cause a greater inflammatory response than lightweight, large pore meshes regardless of where the mesh is located in the human body.<sup>32</sup>

To be sure, the decision to continue using Prolene, despite known complications and the availability of lighter weight, smaller pore mesh, was financial. As Dr. Arnaud put it, Ethicon “want[ed] to be very careful with any modifications of our tape since a change in the mesh would obsolete all the long term clinical results.”<sup>33</sup>

The decision to continue using decades-old mesh has had serious ramifications for patients. The body’s foreign body response to mesh can cause a chronic inflammatory reaction, leading to excessive scarring in and around the mesh, as well as potentially debilitating pain. The

<sup>29</sup> ETH.MESH.05479411

<sup>30</sup> Holste deposition 7-13, p51-53.

<sup>31</sup> ETH.MESH.04941016; HMESH\_ETH\_02030355; ETH.MESH.02340568-ETH.MESH.02340590.

<sup>32</sup> Holste deposition 7-13, p95

<sup>33</sup> ETH.MESH.03911107; Hellhammer deposition, 9-13; Arnaud deposition 7-13, p36-37.

degree of this reaction is directly related to the weight and pore size of the mesh device.<sup>34</sup> Ethicon knew that clinical data shows more chronic pain with heavyweight meshes such as the TVT-S mesh, than with lightweight, partially absorbable meshes. One study found that heavyweight meshes with small pores had to be explanted due to chronic pain more frequently than lightweight meshes with large pores.<sup>35</sup> Indeed, Ethicon's own medical director has stated that the presence of the Prolene mesh can be responsible for chronic pain syndrome in the patient.<sup>36</sup>

#### *Shrinkage and Contraction*

Further, the foreign body reaction, exacerbated by the heavyweight and small pore construction, is chronic, and this chronic inflammation and reaction can lead to mesh contraction and shrinkage.<sup>37</sup> Most studies show less shrinkage in lighter weight meshes, and pore size is one of the most important factors regarding mesh shrinkage.<sup>38</sup> Ethicon knew that all polypropylene meshes experience a 20-50% reduction in their initial size following implantation in the body.<sup>39</sup> Ethicon's own medical director knew that the Prolene mesh can shrink, and generally believed the TVT mesh would shrink approximately 30% post implantation.<sup>40</sup> The mesh contraction and shrinkage can increase the degree of foreign body reaction and mesh degradation, in turn

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<sup>34</sup> Hinoul deposition 4-12, p99; ETH.MESH.08315782; Trial Testimony Piet Hinoul, *Batiste*, March 27, 2014 afternoon, p27; ETH.MESH.05916450

<sup>35</sup> Klosterhalfen, B, Junge, K, Klinge, U, The lightweight and large porous mesh concept for hernia repair. *Expert Rev. Med. Devices*, 2005 2(1)

<sup>36</sup> ETH.MESH.01202102

<sup>37</sup> Vailhe deposition 6-13, p838.

<sup>38</sup> ETH.MESH.02316781; Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. *Surgical Innovation*. 2005, 12(1):T1-T7.

<sup>39</sup> Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. *Surgical Innovation*. 2005, 12(1):T1-T7.

<sup>40</sup> ETH.MESH.03910418

increasing the degree of pelvic pain and pelvic floor dysfunction, such as dyspareunia and difficulty urinating.<sup>41</sup>

Additionally, a recent study has shown that mesh shrinkage is progressive, with a linear evolution of the contraction rate over time, indicating that mesh contraction continues in the patient's body indefinitely into the future.<sup>42</sup> Vaginal mesh contraction can result in vaginal fibrosis, infection, chronic vaginal pain, chronic pelvic pain, vaginal shortening, vaginal narrowing, vaginal extrusion, adjacent organ erosion, and dyspareunia. Feiner and Maher evaluated 17 women with vaginal mesh contraction to demonstrate that the mesh caused the condition. The patients' presenting complaints included severe vaginal pain, dyspareunia, and focal tenderness over contracted portions of mesh on vaginal examination, mesh erosion, vaginal tightness, and vaginal shortening. The patients underwent surgical intervention with mobilization of mesh from underlying tissue, division of fixation arms of the central graft, and excision of contracted mesh. Fifteen of 17 (88%) patients reported a substantial reduction in vaginal pain following explanation, while none of 11 (64%) reported substantial reduction in dyspareunia. However, despite Feiner's relative success with mesh explanation, the adverse effects of transvaginal mesh contraction caused permanent life-altering sequelae in 22-46% of patients in this study.<sup>43</sup> I personally see this type of permanent life-altering sequelae in my daily practice in patients I treat for severe complications related to mesh slings, including Ethicon's TVT-S device.

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<sup>41</sup> De Tayrac, et. al. Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. American Journal of Surgery Vol 193, Issue 4, April 2007, p538-542.

<sup>42</sup> Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J. 2011 Jan;22(1):47-52.

<sup>43</sup> Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. Obstet Gynecol. 2010 Feb;115(2 Pt 1):325-30.; Foon R, Tooze-Hobson P, Latthe P. Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Dec;19(12):1697-706.

### *Scarring*

Polypropylene induces a rapid and acute inflammatory response and strong scar formation. Heavyweight meshes with small pores, such as the Prolene mesh in the TVT-S, induce an intense, chronic foreign body reaction with intensified fibrotic bridging and scar formation.<sup>44</sup> Eventually, the small pores are overwhelmed by the formation of scar tissue, and the entire mesh sling can become encased in a scar plate. This scar plate prevents proper tissue ingrowth.

An increased foreign body reaction with a chronic inflammatory response, followed by the formation of a rigid scar plate, are the primary reasons for the shrinkage and contraction of mesh, which in turn leads to complications including pain and permanent nerve damage.<sup>45</sup> Decreasing the weight of mesh reduces both shrinkage and the inflammatory response. A pore size of at least 1 mm in all directions is needed to prevent the fibrotic bridging and scar plate formation.<sup>46</sup> Despite Ethicon's claims to the contrary, the mesh in the TVT-S has a pore size that is much smaller than 1mm after implantation.<sup>47</sup>

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<sup>44</sup> ETH.MESH.02316781; ETH.MESH.01218361

<sup>45</sup> ETH.MESH.01218361

<sup>46</sup> ETH.MESH.01785259; ETH.MESH.02316781; ETH.MESH.02148431; ETH.MESH.01218361; Klosterhalfen B, Junge K, Klinge U. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan;2(1):103-17; Batke deposition 8-12, p113-114, 118-120, 172-174; Hellhammer deposition 9-13, p403-407; Holste deposition 7-13, p51-53; Holste Deposition 12-12, p89-90; Semin Immunopathol (2011) 33:235-243 - a Scar net formation following large pore (~3 mm) and b scar plate formation following small-pore (~0.3 mm) mesh implantation; Arnaud deposition 9-13, p756-757; ETH.MESH.03021946; ETH.MESH.02587926; ETH.MESH.01752532; ETH.MESH.01785259; ETH.MESH.04941016

<sup>47</sup> ETH.MESH.08315782



Table 1 - Characteristics of Various mesh implants

MESH	Unit Weight (mg/cm <sup>2</sup> ) permanent component	Burst Strength, psi	Maximum Pore Size, mm
PROLENE* Polypropylene Mesh	7.6	234	<1
GYNECARE GYNEMESH* PS Nonabsorbable (PROLENE* Soft Mesh)	4.5	116	2.5
MERSILENE* Polyester Fiber Mesh	3.3	83	<1
VYPRO Mesh	2.5	71 (pre-absorption 90)	4.5
VYPROII Mesh	3.5		3-4
ULTRAPRO* Partially Absorbable Mesh (GYNECARE GYNEMESH M* Mesh)	2.8	90 (pre-absorption 135)	5.0

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The fact that the pore size of the TVT-S is not greater than 1mm in all directions prevents proper tissue integration, which can reasonably be expected to result in the development of a rigid scar plate, leading to, among other things, the potential for increased erosion, pain, nerve entrapment, vaginal shortening, SUI recurrence, urethral obstruction, and dyspareunia.<sup>49</sup> As with other risks, it is well-documented that Ethicon also knew the design of its Prolene mesh could lead to a severe foreign body reaction, excessive scarring and fibrotic bridging, and mesh shrinkage.<sup>50</sup> Nonetheless, Ethicon failed to disclose its own findings, leaving doctors and patients in the dark.

#### 4. Ethicon's Prolene mesh tested positive for cytotoxicity

Cytotoxicity is the quality of being toxic to cells. If a woman's tissues or organs are exposed to a cytotoxic substance, the cells may experience necrosis and die rapidly, or they may undergo a form of controlled cell death known as apoptosis. It is my understanding that it is

<sup>48</sup> ETH.MESH.08315782

<sup>49</sup> Klinge U, Otto J, Muhl T. High Structural Stability of Textile Implants Prevents Pore Collapse and Preserves Effective Porosity at Strain. BioMed Research International. 2015, 953209.

<sup>50</sup> ETH.MESH.05920616; ETH.MESH.04037600; ETH.MESH.05920616; ETH.MESH.05585033; ETH.MESH.05446127; ETH.MESH.05475773; ETH.MESH.04015102; ETH.MESH.04037600; Batke deposition 8-13, p87-88, 113-114, 257-259; Holste deposition 7-13, p51-57; Vailhe deposition 6-13, 182-185.

common for medical devices to be subjected to cytotoxicity testing before they are marketed to doctors and patients.

In support of its application to market the TVT (and then the TVT-S) in the United States, Ethicon did not perform any controlled clinical studies to determine the cytotoxic potential of the TVT, but instead determined that the “long term clinical experience with PROLENE mesh indicated the [prior] cytotoxicity testing would be sufficient to support the biocompatibility of this [mesh] component.”<sup>51</sup> Of course, prior to marketing the TVT device, the Prolene mesh had primarily been used in abdominal hernia repair, and had never before been specifically indicated for use in vaginal tissues. As a result, Ethicon’s conclusion that no new clinical or animal studies were needed to evaluate the cytotoxic potential of the TVT mesh is questionable at best. In fact, to this day, I am not aware of any long-term studies undertaken by Ethicon to determine whether or not the TVT mesh is clinically cytotoxic in women.<sup>52</sup>

Notably, the 2004 Wang study reported a defective healing rate of 2.2% in a series of 670 patients, and a persistent defective healing rate of 1%, which is suggestive of cytotoxicity.<sup>53</sup> Although this study was not published until 2004, Ethicon had been advised that Dr. Wang had experienced 25 erosions from the TVT mesh, which he suspected was due to the body’s rejection of the Prolene mesh in 2002.<sup>54</sup>

The initial Cytotoxicity testing of the TVT prototype device was conducted in March of 1997, and tested all components of the device together for a period of 24 hours. The results of this test indicated the mesh was severely cytotoxic.<sup>55</sup> Ethicon’s own Scotland lab performed

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<sup>51</sup> ETH.MESH.08476210

<sup>52</sup> Robinson deposition 9-13, p1101-1102.

<sup>53</sup> Wang AC, et. al. A histologic and immunohistochemical analysis of defective vaginal tape healing after continence taping procedures: A prospective case-controlled pilot study. American Journal of Obstetrics & Gynecology. 2004;191(6):1868–1874.

<sup>54</sup> ETH.MESH.03736989; ETH.MESH.00409674

<sup>55</sup> ETH.MESH.06851860

follow-up testing, this time testing the needle, heat shrinking tube, sheath, and polypropylene mesh separately. In this test, the polypropylene mesh in the TVT again tested positive for marked cytotoxicity. Ethicon did a third and final test in July of 1997, which finally provided a non-cytotoxic result for the polypropylene mesh. Ethicon relied on the results of this final, July 1997 test in support of its application to market the TVT device, and did not report the two prior positive cytotoxic test results to the FDA, surgeons, or the public.

Ethicon's own Worldwide Medical Director from 2005-2010 was not aware of these positive tests during his tenure.<sup>56</sup> Notably, even the 1997 ISO elution testing showed that the polypropylene mesh in the TVT was moderate to severely cytotoxic, while the ISO agarose diffusion testing showed the mesh was non-cytotoxic. Despite the positive ISO elution testing, and the two previous tests showing the mesh was cytotoxic, Ethicon concluded that "the long history of safe clinical use of polypropylene as a mesh and suture products suggests strongly that the material is inherently biocompatible, and the potential cytotoxicity observed is self-limiting and minimal when compared to the implantation procedure itself."<sup>57</sup>

It is my opinion that based on the 3 positive cytotoxic test results, Ethicon failed in its duty as a reasonable medical device manufacturer by not conducting long-term studies to assess the cytotoxic potential of the TVT mesh, and thus the TVT-S mesh, prior to marketing the device in women. This is particularly true in light of the fact that the Prolene mesh had never before been indicated specifically for use in vaginal tissues, and that there was only limited, short term data for 200 patients on a prototype device available at the time the device was first sold in the United States. In addition, the reports of 25 tape erosions from Dr. Wang in 2002 should have

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<sup>56</sup> Robinson deposition 9-13, p1094-1095.

<sup>57</sup> ETH.MESH.08476210

triggered an additional testing and assessment of the cytotoxic potential of the TVT mesh, but no additional cytotoxic testing was done as a result of these reports.

Although Ethicon claims to have conducted additional cytotoxicity testing prior to FDA approval of the TVT-S, this does not explain the prior positive tests relating to the TVT.<sup>58</sup> And, given the company's history of selectively releasing studies and tests, the 510(k) application hardly puts to rest concerns about Prolene's cytotoxic nature.<sup>59</sup> I have personally seen the clinical effects of the cytotoxic potential of Prolene mesh in my practice. When I have removed Prolene TVT-S mesh from a patient with a mesh erosion, the tissue surrounding the mesh frequently shows evidence of necrosis and cell death. This type of necrosis is typically due to either toxins, infections, trauma, or some combination of the three.

***C. The TVT-S Should Not Be Used in the Pelvic Floor Due to its Defective Design***

1. The TVT-S mesh is laser cut, resulting in a stiffer product and higher incidence of complications

Originally, Ethicon produced its line of TVT products by mechanically cutting the Prolene mesh. With the introduction of TVT-S, the company decided to use lasers to cut the mesh instead

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<sup>58</sup> ETH.MESH.01311841

<sup>59</sup> Ethicon has never conducted a long-term randomized controlled trial with safety as a primary endpoint. (Trial Testimony of Piet Hinoul, *Batiste*, March 27, 2014 afternoon, p57.) In addition, to my knowledge, with respect to studies performed by persons outside of Ethicon, very few are long term randomized controlled studies and none include a primary endpoint of safety. (Robinson deposition 9-13, p977.) There have also been recent studies that suggest that the studies assessing risks of synthetic mid-urethral slings to date are poor and that long term data or evidence lags behind shorter-term studies. (Ford, et. al. Mid-urethral sling operations for stress urinary incontinence in women (review). The Cochrane Library (2015); Blaivas, et. al. Safety considerations for synthetic sling surgery. *Nat. Rev. Urol.* 2015;12 481-509.) Ethicon routinely relies and promotes its products based on long-term data from the original Ulmsten (and later Nilsson) data and studies. However, the studies lack significant data and fail to consider or inquire about many safety risks on the original patient cohort. The Ulmsten/Nilsson data is also biased in that Dr. Ulmsten had financial incentives to obtain certain results with his original studies and received numerous payments, consulting agreements, and royalties related to the TVT and his involvement with Ethicon. (ETH.MESH.03259439; Robinson deposition 9-13, p214-219.)

of machines. According to Ethicon, the change to lasers meant that the new mesh “was about three times stiffer than the machine-cut TVT mesh.”<sup>60</sup>

Predictably, Ethicon conducted no clinical testing on the significance between mechanical cut and laser cut mesh.<sup>61</sup> According to internal Ethicon documents, the company tried to stress that there was nothing clinically significant or “new” about laser cut mesh, in part because “[I]f our results are as we claim [then] why are we changing the mesh with no clinical data?”<sup>62</sup>

Most importantly, the stiffness of the laser-cut mesh can result in additional complications for the patient, as compared to mechanically cut mesh. According to multiple Ethicon employees, for example, stiffer or more rigid mesh can result in a higher incidence of erosion, sexual dysfunction, and voiding dysfunction.<sup>63</sup> A study by Neuman found much higher rates of dyspareunia, attributable to the stiffness of the mesh.<sup>64</sup> In my own practice, I have likewise noticed the more rigid quality of mechanically cut mesh and have identified these types of complications following implantation.

## 2. The TVT-S design is flawed because there is no way to properly tension the device

Proper tensioning of the TVT-S device is critical to ensure that the device is both successful in its intended use to cure stress urinary incontinence and to prevent complications. However, the design of the TVT-S device is flawed because Ethicon cannot properly determine and/or instruct surgeons on the proper placement of the device and, in fact, Ethicon provides nonsensical or misleading instructions on tensioning in its Instructions for Use (“IFU”). It is

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<sup>60</sup> ETH.MESH.01809080; Moalli P. A., Papas N., Menefee S., Albo M., Meyn L., Abramowitch S. D. Tensile properties of five commonly used mid-urethral slings relative to the TVT. *International Urogynecology Journal and Pelvic Floor Dysfunction*. 2008;19(5):655–663.

<sup>61</sup> ETH.MESH.01221735; ETH.MESH.03941617

<sup>62</sup> ETH.MESH.06040171

<sup>63</sup> ETH.MESH.00294195; ETH.MESH.00271641; ETH.MESH.00328895; ETH.MESH.03916716; ETH.MESH.01782949

<sup>64</sup> Neuman M. Transobturator vs. Single-Incision Suburethral Mini-slings for Treatment of Female Stress Urinary Incontinence: Early Postoperative Pain and 3-year Follow Up. *J Min. Invas. Gynecol* 2011 Nov-Dec;18(6):769-73.

known that improper tensioning of slings can lead to failure of the procedure, urinary retention, and well as urinary obstruction. The TVT-S IFU itself states that “[o]ver-correction, i.e., too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction,” and that “[u]nder-correction . . . may result in incomplete or no relief from urinary incontinence.”<sup>65</sup> Too much tension on the mesh can also lead to vaginal or urethral erosions, which the IFU does not mention.<sup>66</sup>

To begin with, the IFU repeatedly refers to the TVT-S as “tension free.” And yet the IFU warns that “over-correction, i.e., too much tension” can result in complications. Presumably, if the tape is “tension free,” the IFU should state that *any* tension can result in complications, not merely the vague phrase “too much.” Worse, the IFU warns of the possibility of “under-correction,” which is presumably impossible with a device that is truly tension free. The IFU informs surgeons to “[e]nsure that the tape is placed with no tension.”

I am not alone in my confusion regarding the tensioning of the TVT-S. Key Opinion Leader Malcolm Frazer reported to Ethicon in November 2007 that “the [TVT-S] IFU is fundamentally misleading. Tension-free, tension-less and placement with no tension are complete misnomers.”<sup>67</sup> Professor Frazer also noted that Ethicon “is now suggesting [outside the IFU] that [the TVT-S] should be much tighter than [the IFU] states, because you assume [the mesh] or tissues may loosen.” (Other Ethicon documents include similar suggestions regarding additional tension.)<sup>68</sup> He further stated that Ethicon had released “inadequate” and “contradictory or confusing statements on tension.”

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<sup>65</sup> ETH.MESH.02340589

<sup>66</sup> ETH.MESH.05529653; ETH.MESH.0016113; ETH.MESH.05529274; ETH.MESH.04044797

<sup>67</sup> ETH.MESH.00311792

<sup>68</sup> ETH.MESH.01782949

The IFU also instructs that the procedure may be performed under general anesthesia. However, the IFU notes that the positioning of the “tension-free tape” should be considered by “cough test or other [undescribed] means.” It is impossible to perform a cough test with a patient under general anesthesia, and Ethicon quite literally provides no guidance for assessing the placement and tensioning of the TVT-S in that situation.

Ethicon’s lack of guidance on tensioning the TVT-S is a repeat of the company’s approach to the original TVT. For example, the fact that the cough test was necessary to properly tension the mesh was noted by Dr. Ulmsten in his original 1996 publication on the TVT, as well as the co-inventor of the TVT, professor Nilsson, who noted that there was a 15% difference in success rates between patients treated with the TVT under local anesthesia with a cough test, and patients under general anesthesia, where no cough test was possible.<sup>69</sup> Despite being aware of this concern, Ethicon launched the TVT with an IFU that informed physicians that the procedure could be performed under general or local anesthesia, yet did not inform physicians that the success rate was much greater if performed under local anesthesia with a cough test. In 2001, Ethicon medical directors recognized the need to have a standardized approach for tensioning the TVT and began work on a product which would avoid excessive tension. This product was never completed, and Ethicon never addressed how to instruct surgeons to properly tension the mesh. Ethicon employees have acknowledged that the TVT line has never truly been tension free, despite years of marketing it as such, and that they cannot accurately describe how to tension the mesh.<sup>70</sup>

Further, the fact that the mesh undergoes changes to its physical characteristics, which may vary from patient to patient, within days of implantation and then continuously throughout

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<sup>69</sup> ETH.MESH.0404851

<sup>70</sup> ETH.MESH.01784428; ETH.MESH.06861473

its time in the human body, means that “proper” tensioning is likely impossible. Ethicon failed to consider or inform physicians that the mesh could shrink from 30-50% once the TVT-S was placed, which obviously affects the final placement and tensioning of the mesh.<sup>71</sup> (Actual shrinkage rates vary based on the individual patient, type of mesh, and location of mesh in the body.)

In sum, Ethicon’s instructions leave the physician with no clear, articulable standard on how to avoid serious adverse reactions like urinary retention or urinary obstruction. Since it is generally impossible to adjust the tensioning more than 24 hours after an operation due to tissue ingrowth, a re-operation surgery is generally required to correct improper tensioning. Therefore, it is particularly important to describe the proper tensioning of the device as part of the product information.

It is my opinion to a reasonable degree of medical certainty that Ethicon has failed in its duty as a reasonable medical device manufacturer by not developing and articulating clear and accurate instructions to surgeons on how to tension the mesh, rendering the device defective. It is also my opinion to a reasonable degree of medical certainty that Ethicon cannot develop and articulate clear and accurate instructions on how to properly tension the mesh as long as defects of heavyweight, small pore, polypropylene mesh exist, as those defects create too many variations in the tensioning of the device to be overcome by instructions, no matter how well designed and articulated they may be.

### 3. The TVT-S is defectively designed in its insertion instruments and technique

Like the TVT and TVT-O, the design of the TVT-S is inherently defective given its use of Prolene mesh, which degrades and deforms in the pelvic floor, leading to serious

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<sup>71</sup> ETH.MESH.03917375



complications as explained above. The TVT-S, moreover, was in fact designed even more poorly than its predicate devices.

Ethicon received FDA approval for the TVT-S under the 510(k) approval process, which is meant for devices that are “substantially equivalent” to a previously approved device. Ethicon asserted that the TVT-S was substantially equivalent to the TVT and TVT-O, but the reality is that the TVT-S is quite different, particularly as far as the implantation technique. The inserters were new,<sup>72</sup> and the procedure, including the “hammock” and “U” methods, was new.<sup>73</sup> As stated previously, the mesh was also the first to be laser cut, which alters the physical characteristics of the mesh as compared to the mechanical cutting utilized for the TVT. As Malcom Frazer put it: the TVT Secur is so “utterly different to the other TVT’s that it probably shouldn’t be called a TVT.”<sup>74</sup> Similarly, Dr. Menachem Neuman, who flew across Europe providing training sessions for Ethicon products, informed the company that “special awareness” should be paid “to the differences between the TVT/TVTO and the TVTS . . . if high cure rates and low complication rates are desired.”<sup>75</sup> (Dr. Neuman provided a number of suggestions regarding TVT-S techniques, none of which were used in an amended IFU.)

The primary problems with the TVT-S, as compared to the predecessor devices, are the insertion tools and techniques. Throughout the TVT-S’s time on the market, Ethicon was aware of complaints relating to difficulty removing the insertion device.<sup>76</sup> For example, in a 2006 email to David Robinson and Dan Smith, among others, Ethicon’s Director of Risk Management Mark Yale described the “potential high rate of occurrence with injuries related to [the TVT-S] not coming off inserter during removal of the inserter, therefore the device is either moved from rest

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<sup>72</sup> Robinson deposition 7-13, p116.

<sup>73</sup> ETH.MESH.17666960; ETH.MESH.02340577

<sup>74</sup> ETH.MESH.00327062.

<sup>75</sup> ETH.MESH.02320486

<sup>76</sup> ETH.MESH.02105223; ETH.MESH.03752501

position or completely pulled out along with inserter.”<sup>77</sup> A Quality Board presentation likewise noted complaints regarding the inserter clinging to the device.<sup>78</sup>

The various problems and potential explanations were summed up in a study by Hota:

The lower overall success of TVT-S could be attributed to the difficulty that was sometimes encountered in the detachment of the introducer from the sling. During the introducer removal process, the original tensioning may have been compromised, as the introducer was moved back and forth in an attempt to release the sling from the introducer....

Another point to consider is that the ends of the TVT-S are intended to be embedded within the obturator internus muscle, as opposed to passing through the obturator membrane as with the TVT-O sling. The TVT-S may theoretically migrate with time, detaching from the obturator internus muscle, whereas with TVT-O, the mesh passes through the obturator membrane as well as the obturator internus and externus muscles and the adductor magnus muscle and therefore may not be dislodged as easily. In other words, the latter approach may create a more reliable anchor for the mesh. In addition, excessive hydrodissection or sharp dissection of the periurethral space may affect the degree of attachment of the absorbable “fleece” on either end of the TVT-S. In addition, the attachment of the fleece could be compromised if a hematoma developed within the obturator internus muscle as a result of the surgical procedure.<sup>79</sup>

The “fleece” material is identified by Ethicon as a combination of polyglactin 910 and poly-p-dioxanone.<sup>80</sup> It was not used in either the TVT or TVT-O, and to my knowledge Ethicon did not perform any studies regarding its use in the pelvic floor. The TVT-S should not have launched without clinical findings showing that the new absorbable materials did not hamper insertion or integration of the device.

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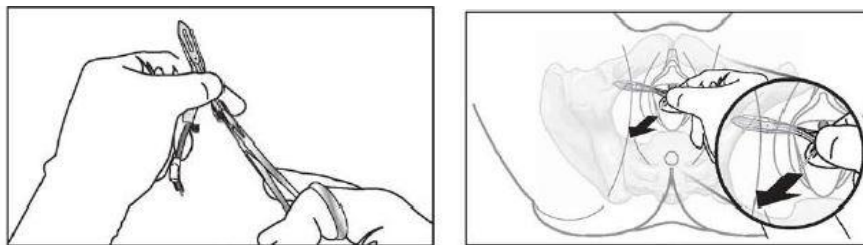
<sup>77</sup> ETH.MESH.0329316

<sup>78</sup> ETH.MESH.06051286

<sup>79</sup> Hota, Lekha S., MD, et al. TVT-Secur (Hammock) Versus TVT-Obturator: A Randomized Trial of Suburethral Sling Operative Procedures. *Female Pelvic Med Reconstr. Surg.* 2012, Jan-Feb;18(1):41-45.

<sup>80</sup> ETH.MESH.02340577

Another issue with the TVT-S insertion tools are the razor-sharp edges on the steel inserters. The Hota study found “an increased incidence of mesh exposure in the TVT-S group,” and theorized that “the sharper edges of the TVT-S introducer potentially create more trauma to the vaginal epithelium and may result in high erosion rates.” A “high-quality review . . . conducted to pool relevant data from randomised controlled trials” is consistent with these findings.<sup>81</sup> The report found that the TVT-S resulted in both more frequent vaginal exposure of mesh and mesh extrusion into the bladder or urethra, as compared to TVT-O-like devices. The TVT-S procedure also made women lose more blood than the TVT-O procedure—a statistically significant amount. Consistent with other studies, the report determined that failure rates among single-incision slings were also higher than with the transobturator approach.<sup>82</sup> The study concluded that “TVT-Secur is inferior to TVT and has already been withdrawn from clinical use.” Once again, Ethicon did not study the potential effects of its razor-sharp instruments. The TVT-S never should have been released with this component; whatever benefits of this razor-sharp tool were clearly outweighed by the risks. It is my opinion that the sharp edges of the inserter are more likely to cause injuries to tissue and more likely to result in mesh erosion and extrusion.



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<sup>81</sup> Nambiar A, Cody JD, Jeffery ST. Single-incision sling operations for urinary incontinence in women (Review). The Cochrane Library, 2014, Issue 6.

<sup>82</sup> Maslow K, Gupta C. Randomized clinical trial comparing TVT Secur system and transvaginal obturator tape for the surgical management of stress urinary incontinence. *Int Urogynecol J* (2014) 25:909–914.

<sup>83</sup> ETH.MESH.02340568



addition, according to Ethicon's Medical Director Piet Hinoul, physicians should be allowed to rely on the safety information in the IFU standing alone.<sup>87</sup> Thus, all risks associated with a medical device must be included in the products' IFU,<sup>88</sup> so that doctors are not left in the dark. I regularly review and rely on IFUs in my on practice. The woefully inadequate IFU for the TVT-S lists the following information in its Adverse Risks Section:

- Punctures or lacerations or injury to vessels, nerves, bladder, urethra, or bowel may occur during instrument passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies and surgical implants, PROLENE mesh and absorbable materials may potentiate or exacerbate an existing infection.
- Over-correction, i.e., too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.
- Under-correction or incorrect placement may result in incomplete or no relief from urinary incontinence.<sup>89</sup>

This is a nearly word-for-word recitation of the Adverse Reactions listed in the early 2000s TVT IFUs, even though, as explained, the products are quite different.<sup>90</sup> By contrast, the current version of the TVT IFU, although still flawed in many ways, lists the following Adverse Reactions:

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.

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<sup>87</sup> Hinoul deposition 1-14, p1207-1208

<sup>88</sup> Beath deposition 7-12, p592; Weisberg deposition 8-13, p959-960.

<sup>89</sup> ETH.MESH.02340589

<sup>90</sup> ETH.MESH.05225354

- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- Recurrence of incontinence
- Bleeding including hemorrhage, or hematoma.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

#### OTHER ADVERSE REACTIONS

- Seroma
- Urge incontinence
- Urinary frequency

- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse.
- Death.<sup>91</sup>

As explained throughout this report and described in more detail below, the IFU for the TVT-S fails to disclose numerous adverse risks, safety information, and warnings that were well-known to Ethicon while the TVT-S was being marketed. Most strikingly, the IFU fails to mention pelvic pain or dyspareunia, which are extremely common complications of mesh implantation. More specifically, the TVT-S IFU fails to warn doctors of the known risks of, among other things: death, acute and chronic pelvic pain, acute and chronic vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, sexual dysfunction, chronic infections, abscess formation, permanent nerve damage, defecatory dysfunction, chronic foreign body reaction, lifelong risk of erosion and extrusion, severe vaginal scarring, inability to remove the device, the need for multiple surgical interventions that carry with them significant risks of morbidity, the development of worsening incontinence and urinary dysfunction, including urinary urgency, urinary urge incontinence, and urinary retention. The IFU also fails to mention, among other things, the research showing that polypropylene is carcinogenic and that Prolene is cytotoxic. And the IFU omits any mention of the fact that Prolene mesh is known to degrade, contract, and shrink.

As described throughout this report, my review of internal documents and the depositions of Ethicon employees reveals that Ethicon was aware of each these risks before or at the time the

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<sup>91</sup> TVT IFU (01/2015), available at <http://hostedv1106.quosavl.com/qb/doc/0nnlfm86hbpkf33bt7pl38flvg>

TVT-S was first marketed and sold.<sup>92</sup> In my opinion, Ethicon's failure to warn of these significant risks resulted in injuries to many women.

Ethicon also failed to include warnings in its IFU related to the increased risk of mesh extrusion in women with prior vaginal surgeries, vaginal atrophy, vaginal injury, and post-operative infection.<sup>93</sup> In addition, Ethicon failed to inform physicians that the TVT-S procedure performed under general anesthesia increases the risk of urinary retention, erosions, and failure of the surgery. Ethicon also failed to mention the risks associated with its new razor-sharp insertor and increased risk of certain complications relating to laser cut mesh. Finally, Ethicon did not tell physicians that the TVT-S device would not work as well in smokers or obese patients.<sup>94</sup> All of these risks should have been disclosed to every surgeon via the original TVT-S IFU. It is inexcusable that no amendment was made to the IFU throughout the TVT-S's marketing period.

In addition to omitting information, Ethicon also downplays and misrepresents significant information in its IFU related to certain mesh properties. For example, despite the significant amount of data regarding mesh-related inflammatory response, the IFU for TVT-S states, "Transitory local irritation at the wound site and a transitory foreign body response may occur." According to the scientific literature, my own clinical experience, deposition testimony of Ethicon employees, and Ethicon's internal documents, the foreign body response is far from "transitory."<sup>95</sup> As Ethicon's Associate Medical Director of Worldwide Customer Quality explained, "[F]rom what I see each day, these patient experiences are not 'transitory' at all."<sup>96</sup>

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<sup>92</sup> Hinoul deposition 6-13, p552; Beath deposition 7-13, p608; Robinson deposition 7-13, p251; ETH.MESH.00312180; ETH.MESH.04081189; ETH.MESH.02089392; ETH.MESH.04099233; ETH.MESH.03910175

<sup>93</sup> Isenberg deposition 11-13, p582-583, ETH.MESH.00159634; ETH.MESH.00203456

<sup>94</sup> ETH.MESH.00640394, Kirkemo deposition 1-14, p556-558.

<sup>95</sup> Robinson deposition 9-13, p1087-1089; Hinoul deposition, 1-14, p1192-1199.

<sup>96</sup> ETH.MESH.04093125



Notably, the word “transient” no longer modifies “foreign body response” in the latest TVT IFU. Further, Ethicon states in its IFU that the polypropylene mesh is not subject to degradation, which is inconsistent with Ethicon’s own internal findings, as described in detail above.

In short, Ethicon not only failed to disclose certain risks associated with the product, it downplayed or inaccurately portrayed known issues related to mesh implantation. Thus, Ethicon prevented physicians from having an appropriate and accurate informed consent discussion with their patients by concealing and misrepresenting this type of information. The information Ethicon provided in patient brochures was no better, similarly downplaying risks, omitting safety information, and improperly equating the TVT-S with the TVT, as though the risks and benefits were the same.<sup>97</sup> As a result, numerous patients have suffered injuries from the TVT-S device that might have been avoided.

#### ***E. Ethicon Failed to Provide Adequate Training for Surgeons Using the TVT-S***

As explained above, the implantation of the TVT-S device was a very different experience for surgeons compared to the TVT and TVT-O. Unfortunately, Ethicon left them in the dark.

For example, in addition to the tension and inserter issues described in this report, Ethicon did not provide surgeons with accurate information regarding the incision size for implantation. The IFU states that the incision size should be 1.0-1.5 cm.<sup>98</sup> But Dr. Arnaud’s “cookbook”<sup>99</sup> and “procedural pearls”<sup>100</sup> suggested a larger incision size, in order to reduce the risk of erosion or exposure.<sup>101</sup> The new size was larger than what was required with older slings.<sup>102</sup>

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<sup>97</sup> ETH.MESH.08003263; ETH.MESH.08003279

<sup>98</sup> ETH.MESH.02340568

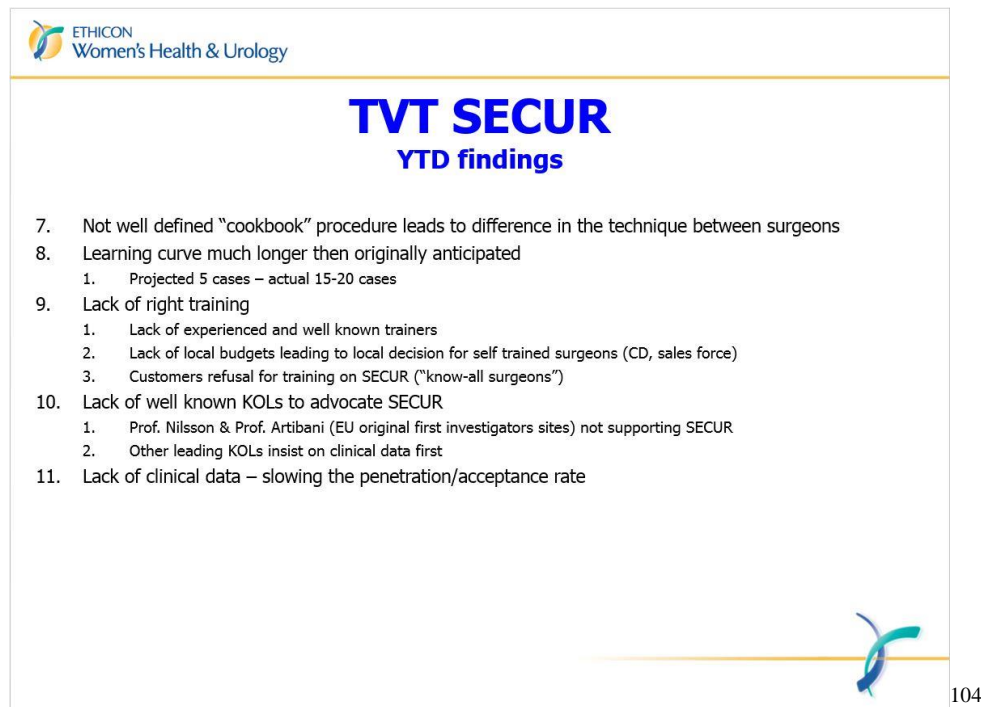
<sup>99</sup> ETH.MESH.03752501; ETH.MESH.00519476

<sup>100</sup> ETH.MESH.07039973

<sup>101</sup> ETH.MESH.17666960

<sup>102</sup> ETH.MESH.17666960

According to their own documents, Ethicon employees were well-aware that surgeons were struggling.<sup>103</sup>



Even Ethicon KOLs needed dozens of surgeries before they became something close to proficient in utilizing the TVT-S.<sup>105</sup>

It is my opinion to a reasonable degree of medical certainty that Ethicon should not have launched the TVT-S without better instructions, and should have provided better training to all surgeons. This issue might have been avoided with extensive pre-launch clinical studies, but none were performed.<sup>106</sup> Internal Ethicon documents suggest that the company continued to

<sup>103</sup> ETH.MESH.0324086; ETH.MESH.0329557; ETH.MESH.00330141; ETH.MESH.03922618; ETH.MESH.00874445; ETH.MESH.00642325; ETH.MESH.02105223; ETH.MESH.03845446; ETH.MESH.01784428; ETH.MESH.03752501

<sup>104</sup> ETH.MESH.02105223

<sup>105</sup> ETH.MESH.02105223; ETH.MESH.03845446; ETH.MESH.04048515


<sup>106</sup> ETH.MESH.00134795

market the product as something that could be easily implanted, for fear of losing market share.<sup>107</sup>

## **V. Conclusion**

In sum, I concur with the results of Ethicon's (unpublished) summary of first-year data on the TVT-S, which showed that nearly a third of women experienced "major" complications: "As long as complications occur at the rate seen in this study . . . the single-incision procedure cannot be recommended as a first line treatment for [SUI]."<sup>108</sup> As explained throughout this report, the TVT-S is a defective device sold with faulty instructions, which never should have been brought to market. As a result of the TVT-S, many women have experienced severe complications that are in many cases irreversible.

Date: January 25, 2016

  
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DANIEL ELLIOTT, M.D.

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<sup>107</sup> ETH.MESH.00858636

<sup>108</sup> ETH.MESH.02916611

# EXHIBIT A

## Curriculum Vitae and Bibliography

### Daniel S Elliott, MD

#### Present Academic Rank and Position

<b>Consultant</b> - Department of Urology, Mayo Clinic, Rochester, Minnesota	07/2003 - Present
<b>Associate Professor of Urology</b> - Mayo Clinic College of Medicine	01/2013 - Present

#### Education

Biola University - BS, Biological Science	1988
School of Medicine, Loma Linda University - MD	1993
Mayo School of Graduate Medical Education, Mayo Clinic College of Medicine - Internship, General Surgery	1993 - 1994
Mayo School of Graduate Medical Education, Mayo Clinic College of Medicine - Resident, Urologic Surgery	1994 - 1999
Baylor College of Medicine - Fellow, Neurourology, Urodynamics and Voiding Dysfunction	1999 - 2000

#### Certification

##### Board Certifications

##### American Board of Urology

Urology	2002 - 2012
Urology/Female Pelvic Medicine and Reconstructive Surgery	2013 - Present

#### Honors and Awards

<b>AUA Resident Award</b> - John D. Silbar North Central Section	10/1998
<b>Urology Grant Recipient</b> - Pfizer Scholars	01/1999
<b>DeWeerd Travel Award Recipient</b> - Awarding Organization	06/1999
<b>Annual Audio-Visual Award - AUA</b> - American Urological Association, Washington, District of Columbia	05/2011
<b>Best Reviewer in 2011 Award - Urodynamics/Incontinence/Female Urology/Neurourology</b> - The Journal of Urology	05/2012
<b>Annual Audio-Visual Award - AUA</b> - American Urological Association, San Diego, California	05/2013
<b>Best Reviewer in 2012 Award - Urodynamics/Incontinence/Female Urology/Neurourology</b> - The Journal of Urology	05/2013
<b>Kelalis Resident Essay Competition</b> - Minnesota Urological Society, Lakeland, Minnesota	02/2015
<b>The North Central Traveling Fellowship Award</b> - North Central Section American Urological Association	11/2015

#### Previous Professional Positions and Major Appointments

<b>Senior Associate Consultant</b> - Department of Urology, Mayo Clinic, Rochester, Minnesota	07/2000 - 06/2003
<b>Assistant Professor of Urology</b> - Mayo Clinic College of Medicine	04/2002 - 12/2012

#### Professional and Community Memberships, Societies, and Services

## Professional Memberships and Services

American Association of Clinical Urologists	
Member	1998 - 2005
American Medical Association	
Member	1991 - 2001
American Urological Association	
Member	2000 - Present
European Association of Urology	
International Member	03/2013 - Present
Section of Female and Functional Urology	
International Member	04/2013 - Present
Section of Genitourinary Reconstructive Surgeons	
International Member	03/2013 - Present
Committee Member	04/2014 - Present
International Continence Society	
Member	2001 - Present
International Pelvic Pain Society	
Member	05/2014 - Present
International Urogynecologic Association	
Member	05/2013 - Present
International Urogynecologic Society	
Member	2003 - Present
Minimally Invasive Robotic Association	
Member	2005 - Present
Minnesota Medical Association	
Member	2002 - Present
Zumbro Valley Medical Society	
Member	2002 - Present
Minnesota Urological Society	
Member	2006 - Present
Olmsted County Medical Association	
Member	2002 - Present
Society for Urodynamics & Female Urology	
Member	2002 - Present
Education Committee	
Committee Member	08/2014 - Present
Society of Laparoendoscopic Surgeons	
Member	2005 - Present
Society of Urologic Prosthetic Surgeons	
Member	2005 - Present

## Journal Responsibilities

### Journal Editorial Responsibilities

Journal of Gynecology and Obstetrics
Editorial Board Member

Journal of Robotic Surgery  
Consulting Editor

#### **Journal Other Responsibilities**

Archives of Gynecology and Obstetrics  
Reviewer  
Canadian Urological Association Journal  
Reviewer  
Cleveland Clinic Journal of Medicine  
Reviewer  
Contemporary Clinical Trials  
Reviewer  
European Journal of Obstetrics & Gynecology and Reproductive Biology  
Reviewer  
European Urology  
Reviewer  
International Urogynecology Journal  
Reviewer  
Journal of Endourology  
Reviewer  
Journal of Investigative Urology  
Reviewer  
Mayo Clinic Health Letter  
Reviewer  
Mayo Clinic Proceedings  
Reviewer  
Nature Clinical Practice Urology  
Reviewer  
Neurourology and Urodynamics  
Reviewer  
Obstetrics & Gynecology International Journal  
Reviewer  
The Journal of Urology  
Reviewer  
Urologia Internationalis  
Reviewer

#### **Educational Activities**

##### **Teaching Intramural**

Prostate Pathology  
Mayo Medical School  
Rochester, Minnesota

03/2005

#### **Institutional/Departmental Administrative Responsibilities, Committee Memberships, and Other Activities**

**Mayo Clinic**

Mayo Clinic Formulary Committee

Committee Member

2000 - 2003

**Mayo Clinic in Rochester**

Department of Urology

Clinical Competency Committee

Chair

01/01/2015 - Present

Committee Member

10/15/2013 - Present

Clinical Practice Committee

Committee Member

2000 - 2004

Education Committee

Committee Member

02/11/2003 -

11/11/2008

Committee Member

10/15/2013 - Present

**Presentations Extramural**

**National or International**

**Invited**

Robotic Urogynecologic Surgery

03/2008

3rd Annual World Robotic Urology Symposium

Orlando, Florida

Robotic Sacrocolpopexy

01/2009

2009 International Robotic Urology Symposium (IRUS), Henry Ford Health System

Las Vegas, Nevada

Current Status Robotic GYN Surgery

01/2010

2010 International Robotic Urology Symposium (IRUS), Henry Ford Health System

Las Vegas, Nevada

Robotic Sacrocolpopexy

09/2010

28th World Congress on Endourology and SWL

Chicago, Illinois

Female Urology

09/2010

28th World Congress on Endourology and SWL

Chicago, Illinois

Optimizing Quality of Life With Regard to Urologic Function After Sacrectomy

01/2013

The 4th Annual Sacral Tumor Study Group Conference, Massachusetts General Hospital

Boston, Massachusetts

A Comparison of Artificial Urinary Sphincter Device Outcomes Among Patients With and Without Diabetes

02/2015

Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)



Scottsdale, Arizona

A Prospective Evaluation of Complications After Artificial Urinary Sphincter Placement and Their Impact on Device Survival 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Autologous Transobturator Urethral Sling Placement for Female Stress Urinary Incontinence 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Effects of Radiation Therapy on Device Survival Among Individuals with Artificial Urinary Sphincters 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Holmium Laser Excision of Genitourinary Mesh Exposure Following Anti-Incontinence Surgery: Minimum 6 Month Follow-up 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Outcomes for Artificial Urinary Sphincter Placement After Prior Male Urethral Sling Failure 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

The Effect of BMI on Primary Artificial Urinary Sphincter Outcomes Among Males with Stress Urinary Incontinence 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Treatment of Bladder and Urethral Mesh Erosion: Remove and Reconstruct 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Urethral Management During Artificial Urinary Sphincter Explantation for Erosion 02/2015  
 Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)  
 Scottsdale, Arizona

Male Urinary Incontinence Management 05/2015  
 Association Fran&#231;aise d&#8217;Urologie (AFU) / American Urological Association (AUA)  
 New Orleans, Louisiana

Negative Impact of Prior Sling on AUS Device Survival 11/2015  
North Central Section of the American Urological Association (AUA)  
United States of America

**Oral**

Long Term Follow-Up of Endoscopically Treated Upper Tract Transitional Cell Carcinoma 04/1995  
American Urological Association Annual Meeting  
Las Vegas, Nevada

Long Term Analysis of 323 AMS 800 Artificial Urinary Sphincters 05/1996  
Urodynamics Subsection Meeting, American Urological Association  
Orlando, Florida

Transabdominal Enzymatic Ablation of the Prostate in the Canine Model: Evaluation for Use for the Treatment of Outflow Obstruction Due to Benign Prostatic Hyperplasia 05/1996  
Urodynamics Subsection Meeting, American Urological Association  
Orlando, Florida

Analysis of Functional Durability of AMS 800 Artificial Urinary Sphincter: The Mayo Clinic Results 04/1997  
American Urological Association Annual Meeting  
New Orleans, Louisiana

Long Term Follow-Up Primary Realignment of Urethral Disruption Following Pelvic Fracture 04/1997  
American Urological Association Annual Meeting  
New Orleans, Louisiana

Does Reoperation on an Artificial Urinary Sphincter Increase the Likelihood for Further Reoperations for Mechanical or Nonmechanical Failure? 06/1998  
American Urological Association Annual Meeting  
San Diego, California

Is Nephroureterectomy Necessary in All Cases of Upper Tract Transitional Cell Carcinoma? Long Term Results of Conservative Endourology Management of Upper Tract Transitional Cell Carcinoma in Individuals with Normal Contralateral Kidneys 05/1999  
American Urological Association Annual Meeting  
Dallas, Texas

Durability of Cadaveric Pubovaginal Sling 06/2001  
American Urological Association Annual Meeting  
Anaheim, California

Does the Addition of Antibiotic Prophylaxis to CIC Alter the Incidence of UTI? 06/2002  
American Urological Association Annual Meeting

Orlando, Florida

Surgical Approach for Placement of SPARC Suburethral Sling 10/2002  
North Central Section, American Urological Association  
Chicago, Illinois

SPARC suburethral sling: technique and results (Video Presentation) 11/2002  
Western Section, American Urological Association  
Kauai, Hawaii

Robotic laparoscopic sacrocolpopexy: new surgical technique for the treatment of 04/2003  
vaginal vault prolapse (Video Presentation)  
American Urological Association  
Chicago, Illinois

08/2004  
Colloquium-ICS/IUGA 2004  
Paris, France

Robotic-Assisted Laparoscopic Management of Vaginal Vault Prolapse 12/2005  
Minimally Invasive Robotics Association  
Innsbruck, Austria

Advancement in Salvage Procedure Following Failed Artificial Urinary Sphincter: 05/2006  
Tandem Transcortical Artificial Urinary Sphincter Cuff Technique (Video  
Presentation)  
American Urological Association  
Atlanta, Georgia

Tandem Transcortical Artificial Urinary Sphincter Cuff Salvage Technique 10/2006  
Following Previous Cuff Erosion and Infection: Surgical Description and Outcome  
Western Section, American Urological Association  
Maui, Hawaii

Assessment of Durability of Robotic Sacrocolpopexy for the Treatment of Vaginal 01/2007  
Vault Prolapse  
Minimally Invasive Robotics Association  
New York, New York

Minimally Invasive Advances: Stress Incontinence 02/2007  
Mayo Clinic Rochester, Department of Urology  
Kohala Coast, Hawaii

Treatment Options for the Failed Sling 02/2007  
Mayo Clinic Rochester, Department of Urology  
Kohala Coast, Hawaii

05/2007  
American Urological Association Annual Meeting

Anaheim, California

Robotics use in Gynecology: the Mayo Clinic experience 06/2007  
 Robotic Surgery: Facts or Fiction?  
 Milano, Italy

Indication and Management of Artificial Urinary Sphincter 10/2007  
 7th Osijek Urological Days  
 Osijek, Croatia

Robotics Use in Gynecology 10/2007  
 7th Osijek Urological Days  
 Osijek, Croatia

Robotic Urogynecologic Surgery 03/2008  
 3rd Annual World Robotic Urology Symposium  
 Orlando, Florida

Latest Advances and Treatment of Complications in Minimally Invasive Treatments 05/2008  
 for Stress Incontinence  
 American Urological Association (AUA)  
 Orlando, Florida

Severe, recurrent bladder neck contracture after prostatectomy: Salvage with 05/2008  
 urethral wall stent (Video and Poster Presentation)  
 American Urological Association (AUA)  
 Orlando, Florida

Surgical Advances of Stress Urinary Incontinence 05/2008  
 Indian American Urological Association (IAUA)  
 Orlando, Florida

Robotic Sacrocolpopexy 01/2009  
 International Robotic Urology Symposium, Henry Ford Health System  
 Las Vegas, Nevada

Management of Complications Following Anti-Incontinence Procedures 02/2009  
 Mayo Clinic, Department of Urology, Rochester Meeting  
 Kona, Hawaii

Minimally Invasive Advances: Stress Incontinence 02/2009  
 Mayo Clinic, Department of Urology, Rochester Meeting  
 Kona, Hawaii

Overactive Bladder: Current Concepts of Management 02/2009  
 Mayo Clinic, Department of Urology, Rochester Meeting  
 Kona, Hawaii

	04/2009
American Urological Association (AUA) Chicago, Illinois	
Robotic repair for vaginal prolapse has significant benefits North Central Section of the AUA - 83rd Annual Meeting Scottsdale, Arizona	11/2009
Current Status Robotic GYN Surgery International Robotic Urology Symposium, Henry Ford Health System Las Vegas, Nevada	01/2010
Robotics for Female Pelvic Reconstruction: Who, When and What? American Urological Association (AUA) San Francisco, California	05/2010
Results of Urethral Wrap As Salvage Treatment Option Following Multiple Failed Artificial Urinary Sphincters North Central Section of the AUA Chicago, Illinois	09/2010
Small intestinal submucosa urethral wrap as a salvage treatment option following multiple failed artificial urinary sphincters Audio-Visual American Urological Association (AUA) Washington, District of Columbia	05/2011
Long-Term Results of Small Intestinal Submucosa at Artificial Urinary Sphincter Placement for Management of Persistent / Recurrent Incontinence Following Multiple Sphincter Failures and Erosions North Central Section of the AUA Rancho Mirage, California	10/2011
OAB Current Concepts and Management Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Transvaginal Mesh Kits Complications and Alternatives Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Treatment and Evaluation of the Complicated Artificial Urinary Sphincter Patient Mayo Clinic Reviews in Urology Kohala Coast, Hawaii	02/2012
Vaginal Mesh for POP: what's the data show? American Urological Association (AUA) Atlanta, Georgia	05/2012

How do different centres perform Robot-assisted-Sacrocolpopexy? 4th Annual Society of European Robotic Gynecological Surgery (SERGS) Marseille, France	06/2012
Comparative Surgical Complications of the Robotic Sacrocolpopexy for Pelvic Organ Prolapse vs. Traditional Transabdominal Sacrocolpopexy European Robotic Urology Symposium (ERUS) London, United Kingdom	09/2012
Infection of Antibiotic-Coated Artificial Urinary Sphincters North Central Section of the AUA Chicago, Illinois	10/2012
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Impact of Patient Obesity on Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Robotic Transvesical Rectourethral Fistula Repair Following a Robotic Radical Prostatectomy (Video Presentation) Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
The Impact of Prior Radiotherapy on Outcomes Following Surgical Repair of a Rectourethral Fistula in Men with Prostate Cancer Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) Las Vegas, Nevada	02/2013
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas American Urological Association (AUA) San Diego, California	05/2013
Impact of Patient Obesity on Robotic Sacrocolpopexy for the Treatment of Vaginal Vault Prolapse American Urological Association (AUA) San Diego, California	05/2013
Long Term Risk for Repeat Anti-Incontinence Surgery following Urethrolysis: A Review of 100 Patients American Urological Association (AUA) San Diego, California	05/2013

Long-Term Outcomes of Patients Undergoing the Standard Versus Modified (5 Points of Fixation, 1 Point of Plication) Technique for Virtue Male Sling Placement (Video Presentation) American Urological Association (AUA) San Diego, California	05/2013
Robotic Transvesical Rectourethral Fistula Repair Following a Robotic Radical Prostatectomy (Video Presentation) American Urological Association (AUA) San Diego, California	05/2013
The Impact of InhibiZone on Artificial Urinary Sphincter Infection Rate American Urological Association (AUA) San Diego, California	05/2013
Impact of patient obesity on robotic sacrocolpopexy for the treatment of vaginal vault prolapse 3rd International Meeting "Challenges in Endourology & Functional Urology" Paris, France	06/2013
Long-Term Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Device Explantation for Erosion and/or Infection South Central Section of the AUA Chicago, Illinois	09/2013
Effect of prior radiotherapy and ablative therapy on surgical outcomes for the treatment of rectourethral fistulas 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013
Impact of patient obesity on robotic sacrocolpopexy for the treatment of vaginal vault prolapse 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013
Long Term Risk for Need to Repeat Anti-Incontinence Surgery Following Urethrolysis: A Review of 144 Patients North Central Section of the AUA Naples, Florida	10/2013
Long-term impact of artificial urinary sphincter reimplantation following prior device explantation for erosion and/or infection 2nd Joint Section Meeting of ESFFU, ESGURS, and ESOU Tübingen, Germany	10/2013
Long-Term Outcomes for Artificial Urinary Sphincter Reimplantation after Explanation for Erosion or Infection North Central Section of the AUA Naples, Florida	10/2013

Simultaneous Cuff-Only Artificial Urinary Sphincter at Augmentation Cystoplasty in Children and Young Adults North Central Section of the AUA Naples, Florida	10/2013
Long-Term Device Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Explantation for Erosion or Infection Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction Miami, Florida	02/2014
Risk Factors for Intraoperative Conversion During Robotic Sacrocolpopexy Society of Urodynamics Female Pelvic Medicine & Urogenital Reconstruction Miami, Florida	02/2014
Results of artificial urinary sphincter reimplantation following previous erosion and/or infection 29th Annual Congress of the European Association of Urology Stockholm, Sweden	04/2014
Autologous Transobturator Mid-Urethral Sling Placement: A Novel Outpatient Procedure for Female Stress Urinary Incontinence (Video Presentation) American Urological Association (AUA) Orlando, Florida	05/2014
Surgical Management of Female Benign Urethral Stricture Disease: A Ten Year Experience American Urological Association (AUA) Orlando, Florida	05/2014
Autologous Transobturator Mid-Urethral Sling Placement for Female Stress Urinary Incontinence (Video Presentation) North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014
Urethral Management at the Time of Artificial Urinary Sphincter Erosion, Is Urethral Catheterization Alone Enough? North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014
Holmium Laser Excision of Genitourinary Mesh Exposure Following Anti-Incontinence Surgery: Minimum 6 Month Follow-up American Urological Association (AUA) New Orleans, Louisiana	05/2015
A Comparison of Artificial Urinary Sphincter Device Outcomes Among Patients with and Without Diabetes North Central Section of the American Urological Association (AUA) Amelia Island, Florida	11/2015



Autologous Transobturator Urethral Sling Placement for Female Stress Urinary Incontinence 11/2015  
North Central Section of the American Urological Association (AUA)  
Amelia Island, Florida

Effects of Radiation Therapy on Device Survival Among Individuals with Artificial Urinary Sphincters 11/2015  
North Central Section of the American Urological Association (AUA)  
Amelia Island, Florida

Infection/Erosion Rates for Artificial Urinary Sphincter Revision After Mechanical Device Failure or Urethral Atrophy 11/2015  
North Central Section of the American Urological Association (AUA)  
Amelia Island, Florida

Long Term Continence Outcomes and Retreatment Rates Following Artificial Urinary Sphincter Placement: An Analysis of 1082 Cases at Mayo Clinic 11/2015  
North Central Section of the American Urological Association (AUA)  
Amelia Island, Florida

The Prospective Impact of Body Mass Index on Primary Artificial Urinary Sphincter Outcomes Among Males with Stress Urinary Incontinence 11/2015  
North Central Section of the American Urological Association (AUA)  
Amelia Island, Florida

# Poster

Robot-Assisted Laparoscopic Sacrocolpopexy for Treatment of High Grade Vaginal Vault Prolapse: Surgical Technique and Initial Experience 09/2007  
29th Congress of the Societe Internationale d'Urologie  
Paris, France

Robot Sacrocolpopexy: A Review of the Learning Curve in Fifty Cases 01/2011  
4th World Congress on Controversies in Urology (CURy)  
Paris, France

Impact of Radiotherapy on Surgical Repair and Outcomes in Patients with Rectourethral Fistula. 06/2012  
67th Annual Meeting of the Canadian Urological Association  
Alberta, Canada

Outcomes and Predictors of Reoperation After Sling Release Surgery 05/2014  
American Urological Association (AUA)  
Orlando, Florida

Term Device Outcomes for Artificial Urinary Sphincter Reimplantation Following Prior Explantation for Erosion or Infection 05/2014  
American Urological Association (AUA)  
Orlando, Florida

Factors Associated with Intraoperative Conversion During Robotic Sacrocolpopexy North Central Section of the American Urological Association (AUA) Chicago, Illinois	09/2014
A Prospective Evaluation of Complications After Artificial Urinary Sphincter Placement and Their Impact on Device Survival American Urological Association (AUA) New Orleans, Louisiana	05/2015
Artificial Urinary Sphincter Outcomes in Octogenarians American Urological Association (AUA) New Orleans, Louisiana	05/2015
Effects of Radiation Therapy on Device Survival Among Individuals with Artificial Urinary Sphincters American Urological Association (AUA) New Orleans, Louisiana	05/2015
Perioperative Impact of Androgen Deprivation Therapy on Artificial Urinary Sphincter Placement Western Section of the AUA Indian Wells, California	10/2015
The Protective Impact of Body Mass Index on Primary Artificial Urinary Sphincter Outcomes Among Males with Stress Urinary Incontinence South Central Section of the American Urological Association (AUA) Scottsdale, Arizona	10/2015

## **Regional**

### **Invited**

Rectocele Office of Women's Health brown bag Rochester, Minnesota	10/2004
Incontinence and Other Urological Issues Radio Broadcast, Hosted by Dr. Thomas Shives HealthLine - KROC Radio Rochester, Minnesota	08/2007
A Practical Approach to Treating Incontinence Clinical Reviews, Rochester Civic Center Rochester, Minnesota	10/2008
A Practical Approach to Treating Incontinence Clinical Reviews, Rochester Civic Center Rochester, Minnesota	11/2008

Incontinence and Other Urological Issues Radio Broadcast, Hosted by Dr. Thomas Shives Medical Edge Weekend - KROC Radio Rochester, Minnesota	03/2010
Urinary Incontinence Radio Broadcast, Hosted by Dr. Thomas Shives Medical Edge Weekend - KROC Radio Rochester, Minnesota	03/2011
Incontinence: Causes and Treatments Prostate Cancer Support Group Rochester, Minnesota	02/2013
Urinary Incontinence Radio Broadcast, Hosted by Dr. Thomas Shives Medical Edge Weekend - KROC Radio Rochester, Minnesota	05/2014
Autologous Transobturator Urethral Sling Placement for Female Stress Urinary Incontinence Minnesota Urological Society (MUS) Spring Seminar Minneapolis, Minnesota	03/2015
Management of Concomitant SUI and Stricture Disease 2015 Mayo Clinic Updates in Urology and Case Conference Program Schedule Rochester, Minnesota	08/2015
Managing the Mesh Mess - Diagnosing and Managing Mesh Complications and Non-Mesh Alternatives 2015 Mayo Clinic Updates in Urology and Case Conference Program Schedule Rochester, Minnesota	08/2015
Surgical Tips to Optimize Outcomes of AUS Placement 2015 Mayo Clinic Updates in Urology and Case Conference Program Schedule Rochester, Minnesota	08/2015
Incontinence Radio Broadcast, Hosted by Tracy McCray Mayo Clinic Radio Rochester, Minnesota	12/2015
<b>Oral</b>	
Paratesticular Angiomyofibroblastoma North Central Section, American Urological Association Minneapolis, Minnesota	09/1995
Does the Degree of Preoperative Elevation PSA Exclude a Patient for	10/1996

Consideration for Radical Retropubic Prostatectomy?  
North Central Section, American Urological Association  
Tucson, Arizona

Does Reoperation of an Artificial Sphincter Place the Patient at an Increased Risk  
for Subsequent Reoperation 10/1998  
North Central Section, American Urological Association  
Amelia Island, Florida

Combined Stent and Artificial Urinary Sphincter for Management of Severe 10/2000  
Recurrent Bladder Neck Contractures and Stress Incontinence after Prostatectomy:  
A Long-Term Evaluation.  
North Central Section, American Urological Association  
Phoenix, Arizona

Does Nocturnal Deactivation of the Artificial Urinary Sphincter Lessen the Risk for 10/2000  
Urethral Atrophy?  
North Central Section, American Urological Association  
Phoenix, Arizona

Is Fascia Lata Allograft Material Trustworthy for Pubovaginal Sling Repair 10/2000  
North Central Section, American Urological Association  
Phoenix, Arizona

Robotics Surgery for Vaginal Prolapse 06/2007  
Controversies in Women's Health Symposium 2007  
Nisswa, Minnesota

# Unclassified

Artificial Urinary Sphincter Mechanical Failures: Is It Better To Replace The Entire 02/2016  
Device Or Just The Malfunctioning Component?  
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction  
(SUFU)

Effects Of Smoking Status On Device Survival Among Individuals Undergoing 02/2016  
Artificial Urinary Sphincter Placement  
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction  
(SUFU)

Long-Term Outcomes Following Artificial Urinary Sphincter Placement: An Analysis 02/2016  
Of 1082 Cases At Mayo Clinic  
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction  
(SUFU)

Long-Term Subjective And Functional Outcomes Of Primary And Secondary 02/2016  
Artificial Urinary Sphincter Implantations Among Men With Stress Urinary  
Incontinence  
Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction  
(SUFU)

Predictors Of Poor Patient Satisfaction Following Primary AUS Placement Among Men With And Without A Prior History Of Radiation Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)	02/2016
Temporal Pattern Of Artificial Urinary Sphincter (AUS) Cuff Erosions Indicating Differing Etiologies Of AUS Cuff Erosions Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)	02/2016

## Visiting Professorship

### Visiting Professorships

Minnesota Urological Society Pyelogram Conference The Artificial Urinary Sphincter: Proper Patient Selection, Implantation and Troubleshooting Lakeland, Minnesota, United States of America	11/07/2014
University of California Irvine AUS: Patient Selection and Complications Management Irvine, California, United States of America	03/16/2015

## Research Grants Awarded

### Completed Grants

#### Federal

Co-Investigator	Selenium and Vitamin E Cancer Prevention Trial (SELECT). Funded by National Cancer Institute. (U10 CA 37429-SELECT)	01/2010 - 12/2010
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#### Industry

Principal Investigator	Are There Histological and Tensile Strength Variations in Autologous, Allograft and SIS Pubovaginal Slings Over Time Using the Rabbit Model. Funded by Mentor Corporation. (MENTOR #5, 1A4575)	10/2002 - 09/2003
Co-Investigator	Single Looped Mechanical Urinary Sphincter: Determination of Required Urethral Constriction Forces to Provide Adequate Urinary Continence in the Canine Model. Funded by Dacomed, Inc.. (Dacomed #1)	10/1995 - 12/1995
Co-Investigator	Clinical Investigation of the Safety and Performance of Timm Medical Technologies' Artificial Urinary Sphincter (TIMM-AUS). Funded by Timm Medical Technologies. (Timm # 1)	06/1999 - 02/2005
Co-Investigator	A Randomized, Double-Blind, Parallel-Group Study to Investigate the Effects of a Single Oral Dose of L-753099 Compared to Placebo and Tolerodine on Urodynamic Parameters in Healthy Male Volunteers. Funded by Merck & Co., Inc.. (Merck 138)	07/1999 - 12/2003
Co-Investigator	The Safety, Local Tolerability, Pharmacokinetics, and Risk Benefit of Oxybutynin Transvaginal Rings (TVR) in Women with a History of Overactive Bladder. Funded by Advanced Biologics. (BIOLOGICS #1)	01/2001 - 12/2003

Co-Investigator An Eight-Week, Double-Blind, Randomized, Parallel Group Design, 06/2001 - 07/2003  
Multicenter Study of FLOMAX Capsules, 0.4 mg Daily Vs. Placebo, in  
Female Patients w/ Lower Urinary Tract Symptoms (LUTS) w/ a  
Significant Component of Voiding Symptoms. Funded by Boehringer  
Ingelheim. (BOEHRINGER #34)

Co-Investigator Veritas Collagen Matrix Urological Sling Postmarketing Clinical Study 10/2001 - 09/2003  
Protocol. Funded by Bio-Vascular, Inc.. (BIOVASCULAR #1)

**Mayo Clinic**

Principal Transurethral Enzymatic Ablation of the Prostate (TEAP); Short-term 09/1995 - 12/2003  
Investigator Concentration Study. Funded by Department Discretionary Funds.  
(Immuno 2)

## Bibliography

### Peer-reviewed Articles

1. Gleason PE, **Elliott DS**, Zimmerman D, Smithson WA, Kramer SA. Metastatic testicular choriocarcinoma and secondary hyperthyroidism: case report and review of the literature. J Urol. 1994 Apr; 151(4):1063-4. PMID:8126794
2. **Elliott DS**, Blute ML, Patterson DE, Bergstralh EJ, Segura JW. Long-term follow-up of endoscopically treated upper urinary tract transitional cell carcinoma. Urology. 1996 Jun; 47(6):819-25. PMID:8677570 DOI:10.1016/S0090-4295(96)00043-X
3. **Elliott DS**, Barrett DM. Long-term followup and evaluation of primary realignment of posterior urethral disruptions. J Urol. 1997 Mar; 157(3):814-6. PMID:9072573
4. **Elliott DS**, Barrett DM. The artificial urinary sphincter in the female: indications for use, surgical approach and results. Int Urogynecol J Pelvic Floor Dysfunct. 1998; 9(6):409-15. PMID:9891964
5. **Elliott DS**, Barrett DM. Mayo Clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. J Urol. 1998 Apr; 159(4):1206-8. PMID:9507835
6. Brown JA, **Elliott DS**, Barrett DM. Postprostatectomy urinary incontinence: a comparison of the cost of conservative versus surgical management. Urology. 1998 May; 51(5):715-20. PMID:9610584
7. **Elliott DS**, Barrett DM. The artificial genitourinary sphincter. Digital Urology Journal. 1998 Jul.
8. **Elliott DS**, Timm GW, Barrett DM. An implantable mechanical urinary sphincter: a new nonhydraulic design concept. Urology. 1998 Dec; 52(6):1151-4. PMID:9836575
9. **Elliott DS**, Boone TB. Urethral devices for managing stress urinary incontinence. Journal of Endourology. 2000 Feb; 14(1):79-83. PMID:10735576
10. **Elliott DS**, Barrett DM. Artificial urinary sphincter implantation using a bulbous urethral cuff: perioperative care. Urol Nurs. 2000 Apr; 20(2):89-90, 95-8. PMID:11998129
11. Frank I, **Elliott DS**, Barrett DM. Success of de novo reimplantation of the artificial genitourinary sphincter. J Urol. 2000 Jun; 163(6):1702-3. PMID:10799164
12. Petrou SP, **Elliott DS**, Barrett DM. Artificial urethral sphincter for incontinence. Urology. 2000 Sep 1; 56(3):353-9. PMID:10962293
13. **Elliott DS**, Boone TB. Is fascia lata allograft material trustworthy for pubovaginal sling repair? Urology. 2000 Nov 1; 56(5):772-6. PMID:11068297
14. **Elliott DS**, Boone TB. Recent advances in the management of the neurogenic bladder. Urology. 2000 Dec 4; 56(6 Suppl 1):76-81. PMID:11114567
15. **Elliott DS**, Boone TB. Combined stent and artificial urinary sphincter for management of severe recurrent bladder neck contracture and stress incontinence after prostatectomy: a long-term evaluation. J Urol. 2001 Feb; 165(2):413-5. PMID:11176385 DOI:10.1097/00005392-200102000-00014
16. **Elliott DS**, Mutchnik S, Boone TB. The "bends" and neurogenic bladder dysfunction. Urology. 2001 Feb; 57(2):365. PMID:11182361
17. Kim IY, **Elliott DS**, Husmann DA, Boone TB. An unusual presenting symptom of sarcoidosis: neurogenic

bladder dysfunction. J Urol. 2001 Mar; 165(3):903-4. PMID:11176503

18. Petrou SP, **Elliott DS**. Artificial urethral sphincter for incontinence in adults. Drugs Today (Barc) 2001 Apr; 37(4):237-244. PMID:12768224
19. **Elliott DS**, Barrett DM, Gohma M, Boone TB. Does nocturnal deactivation of the artificial urinary sphincter lessen the risk of urethral atrophy? Urology. 2001 Jun; 57(6):1051-4. PMID:11377302
20. **Elliott DS**, Segura JW, Lightner D, Patterson DE, Blute ML. Is nephroureterectomy necessary in all cases of upper tract transitional cell carcinoma? Long-term results of conservative endourologic management of upper tract transitional cell carcinoma in individuals with a normal contralateral kidney. Urology. 2001 Aug; 58(2):174-8. PMID:11489692
21. Lightner DJ, **Elliott D**, Gillett M. Surgeon's corner. Transvaginal culdoplasty for posthysterectomy vaginal vault prolapse. Contemp Urol. 2003 Sep; 15(9):15-22. PMID:0
22. DiMarco DS, **Elliott DS**. Tandem cuff artificial urinary sphincter as a salvage procedure following failed primary sphincter placement for the treatment of post-prostatectomy incontinence. J Urol. 2003 Oct; 170(4 Part 1):1252-4. PMID:14501735
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24. Di Marco DS, Chow GK, Gettman MT, **Elliott DS**. Robotic-assisted laparoscopic sacrocolpopexy for treatment of vaginal vault prolapse. Urology. 2004 Feb; 63(2):373-6. PMID:14972496 DOI:10.1016/j.urology.2003.09.033
25. Dora CD, Dimarco DS, Zobitz ME, **Elliott DS**. Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery. J Urol. 2004 May; 171(5):1970-3. PMID:15076323 DOI:10.1097/01.ju.0000121377.61788.ad
26. **Elliott DS**, Frank I, DiMarco DS, Chow GK. Gynecologic use of robotically assisted laparoscopy: sacrocolpopexy for the treatment of high-grade vaginal vault prolapse. Am J Surg. 2004 Oct; 188(4A Suppl S):52S-56S. PMID:15476652
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28. **Elliott DS**, Chow GK, Gettman M. Current status of robotics in female urology and gynecology. World J Urol. 2006 Jun; 24(2):188-92. Epub 2006 Mar 24. PMID:16557388 PMCID:0 DOI:10.1007/s00345-006-0071-5
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#### Abstracts

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2. **Elliott DS**, Barrett DM. Long term followup and evaluation of primary realignment of posterior urethral disruption. (Abstract 855). J Urol. 1997 Apr; 157(4 Suppl):219.
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8. Kausik S, **Elliott DS**. External beam radiation and its effect on artificial urinary sphincter long-term function. American Urological Association Annual Meeting, Orlando, Florida. 2002 Jun.
9. DiMarco D, **Elliott DS**. Long term results of tandem urethral cuff for the treatment of male incontinence following RRP. North Central Section, American Urological Association, Chicago, Illinois. 2002 Oct.
10. Dora C, **Elliott DS**. Preliminary results of SPARC suburethral sling. North Central Section, American Urological Association, Chicago, Illinois. 2002 Oct.
11. Dimarco DS, Chow GK, Gettman MT, **Elliott DS**. Robotic-assisted laparoscopic sarcocolpopexy (Abstract MP 18/17). J Endourol. 2004 Nov; 18(Suppl 1):A109.



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27. Linder B, Piotrowski J, Zieglemann M, Miest T, Rivera M, Ogle C, **Elliott D**. A prospective evaluation of complications after artificial urinary sphincter placement and their impact on device survival. Neurourol Urodyn. 2015 Feb; 34:S26.

28. Linder B, **Elliott D**. Autologous transobturator urethral sling placement for female stress urinary incontinence. *Neurourol Urodyn*. 2015 Feb; 34:S50.
29. Rivera M, Ziegelmann M, Linder B, Viers B, Rangel L, **Elliott D**. Effects of radiation therapy on device survival among individuals with artificial urinary sphincters. *Neurourol Urodyn*. 2015 Feb; 34:S80-1.
30. Ogle C, Linder B, **Elliott D**. Holmium laser excision of genitourinary mesh exposure following anti-incontinence surgery: minimum 6 month follow-up. *Neurourol Urodyn*. 2015 Feb; 34:S26.
31. Ziegelmann M, Linder B, Rivera M, Ogle C, **Elliott D**. Outcomes for artificial urinary sphincter placement after prior male urethral sling failure. *Neurourol Urodyn*. 2015 Feb; 34:S26-7.
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\* Indicates that the primary author was a mentee of this author.

**Compensation**

I am compensated for investigation, study, and consultation in this case at the rate of  
\$700.00 per hour.

/s/ Daniel Elliott

DANIEL ELLIOTT, M.D.



# EXHIBIT B

### **Prior Testimony**

As noted below, I have given testimony and provided expert reports in numerous Ethicon transvaginal mesh cases over the past few years. All of my testimony, opinions, and materials therein are hereby incorporated into this report by reference.

*Coloplast A/S v. Generical Medical Devices*; United States District Court – Western District of Washington at Tacoma Case No. C10-227BHS

*Linda Gross et al. v. Gynecare, et al.*; Superior Court of New Jersey Law Division – Middlesex County Case No. MID-L-9131-08– Report & Deposition

*Diane Bellew v. Ethicon et al.*; United States District Court, Southern District of West Virginia Case No. 2:12-cv-22473 – Report, Deposition & Trial

*Janice L. St. Cyr v. C.R. Bard, Inc. et al.*; United States District Court, Southern District of West Virginia Case No. 2:14-cv-02313

*Kathleen Stanbrough v. C.R. Bard, Inc. et al.*; United States District Court, Southern District of West Virginia Case No. 2:14-cv-06937

*Sheila Sutton v. C.R. Bard, Inc. et al.*; United States District Court, Southern District of West Virginia Case No. 2:14-cv-00105

*Pamela Ailey v Cook Medical, Inc., et al.*; United States District Court, Southern District of West Virginia Case No. 2:13-CV-20496

*Patricia L. Hammons v. Ethicon, Inc., et al.*; Philadelphia County Court of Common Pleas Case No. 0003913 – Report & De Bene Esse

*Dale Watkins et al. vs. Ethicon, Inc. et al.*; Superior Court of New Jersey Law Division – Bergen County Case No. BER-L-13787-14 MCL – Report & Deposition

*Mullins et al v. Ethicon, Inc., et al.*; Southern District of West Virginia Charleston Division Case No. 2:12-cv-02952 – Report & Deposition

# EXHIBIT C

Date	Bates - Begin	Bates - End	Description
3/2/1981	ETH.MESH.15958524	ETH.MESH.15958524	Guidoin Lab Notebook Page/Image
3/17/1982	ETH.MESH.15958396	ETH.MESH.15958399	Guidoin Lab Notebook Page/Image
3/23/1983	ETH.MESH.15955438	ETH.MESH.15955473	Guidoin Lab Notebook Page/Image
3/25/1983	ETH.MESH.15958410	ETH.MESH.15958432	Guidoin Lab Notebook Page/Image
5/25/1983	ETH.MESH.15958400	ETH.MESH.15958404	Guidoin Lab Notebook Page/Image
8/14/1984	ETH.MESH.15958433	ETH.MESH.15958444	Guidoin Lab Notebook Page/Image
9/27/1984	ETH.MESH.15958408	ETH.MESH.15958409	Guidoin Lab Notebook Page/Image
11/5/1984	ETH.MESH.15958452	ETH.MESH.15958469	Guidoin Lab Notebook Page/Image
11/7/1984	ETH.MESH.15958405	ETH.MESH.15958407	Guidoin Lab Notebook Page/Image
3/11/1985	ETH.MESH.15958445	ETH.MESH.15958451	Guidoin Lab Notebook Page/Image
5/30/1985	ETH.MESH.09746373	ETH.MESH.09746448	Memo N.R. Cholvin to Dr. R.L. Kronenthal, et al. re Protocol for 10 Year In Vivo Study of Monofilament Sutures
1/20/1988	ETH.MESH.15144996	ETH.MESH.15144996	Report: Quebec Explants
1/20/1988	ETH.MESH.00004755	ETH.MESH.00004755	Guidoin Explant Study notes
8/10/1990	ETH.MESH.11336474	ETH.MESH.11336487	Five Year Report re Ten Year In Vivo Suture Study
3/8/1991	N/A	N/A	FDA Device Labeling Guidance #G91-1 (Blue Book Memo)
3/8/1991			FDA Device Labeling Guidance #G91-1
1/1/1997	ETH.MESH.00371572	ETH.MESH.00371573	Alex C. Wang "Tension-Free Vaginal Tape (TVT) for Urinary Stress Incontinence - A Preliminary Report"
2/13/1997	ETH.MESH.08696050	ETH.MESH.08696055	Consulting & Technology Agreement between Johnson & Johnson International and Professor Ulf Ivar Ulmsten
2/26/1997	ETH.MESH.08696084	ETH.MESH.08696134	Medscan Agreement
3/1/1997	N/A	N/A	Medical Device Reporting for Manufacturers by Department of Health and Human Services, Public Health Services, FDA

6/13/1997	ETH.MESH.12009095	ETH.MESH.12009101	Ulmsten Preliminary report of Multicentre Study on TVT
8/8/1997	ETH.MESH.06852120	ETH.MESH.06852129	Cytotoxicity Risk Assessment
8/29/1997	N/A	N/A	1997 Marlex MSDS
9/11/1997	ETH.MESH.09747728	ETH.MESH.09747728	Linsky email re TVT (Ulmsten) -510k submission
9/16/1997	ETH.MESH.09747632	ETH.MESH.09747643	PAC Meeting Review - Tension Free Vaginal Tape (TVT) Ulmsten Device
10/1/1997	ETH.MESH.09747724	ETH.MESH.09747725	Linsky C email re Recommendation not to Accelerate TVT Program
1/11/1998	ETH.MESH.03658577	ETH.MESH.03658577	Presentation: Biocompatibility of ULTRAPRO by Joerg L. Holste, DVM
1/28/1998	ETH.MESH.00371496	ETH.MESH.00371594	FDA 510(k) clearance letter
1/28/1998	N/A	N/A	Tension Free Vaginal Tape (TVT) System 510(k)
2/18/1998	HMRDH_ETH_00133261	HMRDH_ETH_00133262	Liu email chain re Prolene Mesh Redesign
6/17/1998	ETH.MESH.09266659	ETH.MESH.09266660	Tang email chain re Prolene Mesh Update
7/30/1998	ETH.MESH.00130934	ETH.MESH.00130941	Kaminski Memo re summary of key point from US Marketing Research Study on TVT
8/17/1998	ETH.MESH.09264945	ETH.MESH.09264946	Rousseau Memo to Lessig re Prolene Mesh Re-Design Project
8/18/1998	ETH.MESH.12009027	ETH.MESH.12009035	Rowan email re GyneMesh II New Mesh Design w/attachment
9/7/1998	ETH.MESH.09266668	ETH.MESH.09266671	Tang email chain re Mesh 3
9/17/1998	ETH.MESH.07877085	ETH.MESH.07877085	Lessig email re PROLENE Mesh Redesign Project
9/23/1998	ETH.MESH.09266465	ETH.MESH.09266466	D Aversa email chain re Prolene Mesh Sheets Research
3/30/1999	ETH.MESH.00203456	ETH.MESH.00203456	Gillick email chain re TVT insert
4/8/1999	ETH.MESH.14410703	ETH.MESH.14410741	Toth Memo to Copy Review Team re New Construction PROLENE polypropylene mesh Sales Aid and Demo Device

5/3/1999	ETH.MESH.11283974	ETH.MESH.11283974	Lehe email re Reisebericht: TVT - Brainstorming (PD 98/5)
5/4/1999	ETH.MESH.14410846	ETH.MESH.14410851	Toth email chain re New Construction PROLENE polypropylene mesh Pre-Launch Memo w/attachment
6/9/1999	ETH.MESH.11283949	ETH.MESH.11283951	Hoepffner email chain re Trip report -- meeting with Dr. Ulstem
6/24/1999	ETH.MESH.14411026	ETH.MESH.14411040	Toth, JL Memo to Copy Review Team re TVT Tension-free Vaginal Pate Press Briefing Presentation
7/13/1999	ETH.MESH.03456775	ETH.MESH.03456776	Product Pointer for TVT Tension-free Vaginal Tape
8/18/1999	ETH.MESH.09275875	ETH.MESH.09275876	Rousseau email re Samples of PROLENE Mesh
9/15/1999	ETH.MESH.04193990	ETH.MESH.04193993	Major Executive Committee Actions July 20, 1999 through September 15, 1999
12/2/1999	ETH.MESH.09346419	ETH.MESH.09346420	Memo to R. Rousseau re Biocompatibility Risk Assessment for Soft PROLENE Mesh
12/2/1999	ETH.MESH.09346417	ETH.MESH.09346418	Biocomp risk assessment GPS revised
1/4/2000	ETH.MESH.09273600	ETH.MESH.09273601	Dormier email chain re LcBlanc CME Live on Medscape
2/24/2000			Labelling for Medical Devices by SG1 and endorsed by The Global Harmonization Task Force
4/5/2000	ETH.MESH.17661347	ETH.MESH.17661347	Angleitner email chain re TVT Product complaint w/handwritten notes
4/14/2000	ETH.MESH.17661336	ETH.MESH.17661499	Hellberg communication re Product Complaint Form
4/17/2000	ETH.MESH.05529274	ETH.MESH.05529275	Gynecare TVT Tension-free Support for Incontinence
5/26/2000	ETH.MESH.06852118	ETH.MESH.06852129	Biocompatibility Review
6/1/2000	ETH.MESH.00658177	ETH.MESH.00658198	Surgeon's Resource Monograph

6/6/2000	ETH.MESH.05493965	ETH.MESH.05493999	"Meshes in Pelvic Floor Repair - Findings from literature review and conversations/interviews with surgeons" prepared by Brigitte Hellhammer
6/9/2000	ETH.MESH.00160612	ETH.MESH.00160625	Toth Memo re Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure (TVT016)
7/7/2000	ETH.MESH.0137272	ETH.MESH.01137293	Incontinence/Pelvic Floor Management GYNECARE TVT Tension-free Support for Incontinence 2001 Marketing Plan
7/12/2000	ETH.MESH.01317515	ETH.MESH.01317524	TVT-2 needles Introducer Revision 8
8/14/2000	ETH.MESH.00158559	ETH.MESH.00158590	TVT Professional Education Tensioning
8/17/2000	ETH.MESH.10216874	ETH.MESH.10216875	Slusser email chain re AUGS lecture/content of discussion
8/18/2000	ETH.MESH.08793648	ETH.MESH.08793648	Study Justification: Gynecare Clinical Research Program 2001 spreadsheet
8/21/2000	ETH.MESH.03909708	ETH.MESH.03909713	ARnaud A email chain re Pelvic floor repair Procedural Strategy
8/21/2000	ETH.MESH.08793646	ETH.MESH.08793647	Isenberb email re WOW Business Plan -- 2001, Clinical Research
8/28/2000	ETH.MESH.03736578	ETH.MESH.03736578	Memo Marty Weisberg to Rick Isenberg re discussion with redacted
9/6/2000	ETH.MESH.09746615	ETH.MESH.09746617	Ltt Nilsson from Zauberman re Surgeon Panel
9/22/2000	ETH.MESH.00143697	ETH.MESH.00143699	Memo from J.L. Toth to Copy Review Team re "A three-year follow up of tension free vaginal tape for surgical treatment of the female stress urinary incontinence" Article (TVTO15 - REVIEW FOR REPRINT
9/22/2000	ETH.MESH.00143700	ETH.MESH.00143702	Memo from J.L. Toth to Copy Review Team re "A three-year follow up of tension free vaginal tape for surgical treatment of the female stress urinary incontinence" Article (TVTO15 - REVIEW FOR REPRINT

11/1/2000	ETH.MESH.03736932	ETH.MESH.03736932	Memo Marty Weisberg to Rick Isenberg re Complaint
1/16/2001	HMESH_ETH_00946830	HMESH_ETH_00946838	Dormier email chain re Corporate Product Characterization December Monthly Report
2/6/2001	HMESH_ETH_02944363	HMESH_ETH_02944364	Vypro for Pelvic Floor Repair agenda
2/13/2001	ETH.MESH.03915380	ETH.MESH.03915380	Email Axel Arnaud to Dr Uwe re Dr Lucente/TVT Procedure Improvements/Prevention of Overstretching
2/28/2001	N/A	N/A	Phillips Sumika 2001 Marlex MSDS
4/11/2001	ETH.MESH.00161129	ETH.MESH.00161130	Toth Memo re Gynecare TVT Tension-free Support for Incontinence Competitive Mesh Products - Product Pointer
4/17/2001	ETH.MESH.00161131	ETH.MESH.00161132	Product Pointer: Gynecare TVT Tension-free Support for Incontinence: A Synthetic Sling with Erosion Rates No Higher Than Autologus Slings
4/23/2001	ETH.MESH.10181921	ETH.MESH.10181922	Ulmsten ltt Ostergard re Cannes meeting
5/14/2001	ETH.MESH.01317508	ETH.MESH.01317613	Target Sheet Design History: DH0263-DH0278
5/14/2001	ETH.MESH.02607272	ETH.MESH.02607814	Design History CH1035 (bk2) - DH1036 (bk5)
6/1/2001	ETH.MESH.05494064	ETH.MESH.05494066	Hellhammer email chain re WG: TVT instructions for use
6/1/2001	ETH.MESH.12002601	ETH.MESH.12002601	Angelini L email re TVT improvements
6/6/2001	ETH.MESH.03905472	ETH.MESH.03905477	Weisberg, M email chain re TVT recommendation from Dr. Alex Wang
6/7/2001	ETH.MESH.00144270	ETH.MESH.00144278	TVT 20010607 Gynecare TVT Tension-free Support for Incontinence
6/18/2001	ETH.MESH.08798099	ETH.MESH.08798110	2002-2003 US Marketing Plan for Gynecare TVT Tension-free Support for Incontinence
6/21/2001	HMESH_ETH.00958003	HMESH_ETH.00958005	TVT Recommendations from Dr. Wang - Meeting Minutes of June 21, 2001
6/22/2001	ETH.MESH.02089392	ETH.MESH.02089399	Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes



6/26/2001	HMESH_ETH_00958014	HMESH_ETH_00958015	Luscombe email chain re TVT recommendations from Dr. Wang
7/3/2001	ETH.MESH.00144304	ETH.MESH.00144331	Presentation: TVT Sales Force Update @ Divisional Meeting
7/6/2001	ETH.MESH.17606501	ETH.MESH.17606502	Dormier E email chain re Vypro vs Soft Prolene Mesh for Pelvic Floor Repair
8/2/2001	ETH.MESH.00764323	ETH.MESH.00764325	5-Year Press Release Draft: Long-term Data Proves Safety and Efficacy of GYNECARE TVT Tension-free Support Treating Stress Urinary Incontinence
8/15/2001	ETH.MESH.00864131	ETH.MESH.00864133	Luscombe B email chain re Aug 11 program
9/28/2001	ETH.MESH.09306898	ETH.MESH.09306910	2002 US Marketing Plan for TVT
10/1/2001	ETH.MESH.03909721	ETH.MESH.03909733	New Products Development Gynecare Products by Axel Arnaud
1/16/2002	ETH.MESH.00029963	ETH.MESH.00029966	Luscombe email re ALERLT!!! Professional Ads for GYNECARE TVT !!!!! w/attachments
1/28/2002	ETH.MESH.04384185	ETH.MESH.04384188	Particle Release Characteristics of Clear and Blue TVT Mesh Corporate Product Characterization
1/28/2002	ETH.MESH.02613804	ETH.MESH.02613805	Corporate Product Characterization - Comparison of Particle Characteristics of Clear and 50% Blue PROLENE Mesh of TVT Device
3/28/2002	ETH.MESH.08695896	ETH.MESH.08695896	Letter from Howard Zauberman (Ethicon) to Mr. Jan Johansson (Director, Eurosund Medical AB)
4/25/2002	ETH.MESH.08793552	ETH.MESH.08793553	Email Ettore Carino to Kimberly Mullarkey re FW: DTC Review
4/25/2002	ETH.MESH.01317510	ETH.MESH.01317514	DDSA Re-Evaluation for TVT
5/1/2002	ETH.MESH.03907468	ETH.MESH.03907469	"Second Generation TVT" by Axel Arnaud
6/7/2002	ETH.MESH.03735432	ETH.MESH.03735433	Emails Richard Isenberg to Dr Wang re concerns for patient safety
6/7/2002	ETH.MESH.00409674	ETH.MESH.00409675	Email Richard Isenberg to Greg Jones, et al. re Dr Alex Wang, Taiwan--Reports of "tape rejection" with TVT

6/10/2002	ETH.MESH.03483690	ETH.MESH.03483693	Email Mark Yale re Wang's rejections
6/28/2002	ETH.MESH.01264260	ETH.MESH.01264260	Lawler T email re Polypropylene Mesh
7/2/2002	ETH.MESH.05961204	ETH.MESH.05961211	Corrective/Preventive Action TVT Tape
7/2/2002	ETH.MESH.05961197	ETH.MESH.05961203	Corrective/Preventive Action TVT Tape
7/9/2002	ETH.MESH.04927339	ETH.MESH.04927340	FDA Communication re 522 Prosima
8/8/2002	ETHMESH.OHARA.00000001	ETHMESH.OHARA.00000156	O'Hara Employment Eligibility Verification Form
8/8/2002	ETHMESH.OHARA.00000157	ETHMESH.OHARA.00000303	O'Hara personnel file docs
9/11/2002	ETH.MESH.05961212	ETH.MESH.05961234	Corrective/Preventive Action TVT Tape
9/16/2002	ETH.MESH.11773498	ETH.MESH.11773499	Email Shannon Campbell to Shelley Copeland, et al. re Ft. Worth Advanced TVT dinner feedback
9/27/2002	ETH.MESH.00030025	ETH.MESH.00030026	Letter to Dr. James Meeuwesen of Pueblo, CO from Scott Jones
10/4/2002	ETH.MESH.00409657	ETH.MESH.00409658	Rejection of Polypropylene Tape After the Tension-Free Vaginal Tape (TVT) Procedure by Alex C. Wang, MD
10/4/2002	ETH.MESH.03910208	ETH.MESH.03910210	Report: Visit to Pr Jean de Leval
12/3/2002	ETH.MESH.00409670	ETH.MESH.00409670	Email Martin Weisberg to Mark Sumeray et al. re Prolene rejection
1/9/2003	ETH.MESH.05961304	ETH.MESH.05961315	Corrective/Preventive Action TVT Tape
1/27/2003	ETH.MESH.00766975	ETH.MESH.00766976	DTC Focus Group Summary
1/31/2003	ETH.MESH.01808311	ETH.MESH.01808318	Tracey M Trip Report
2/5/2003	ETH.MESH.01808310	ETH.MESH.01808310	Tracey M email re Trip Report Format Mulberry 22Jan2003
2/13/2003	ETH.MESH.06866920	ETH.MESH.06866920	Presentation - Ultrasonic Slitting of TVT Mesh Technical Review
2/14/2003	ETH.MESH.06873447	ETH.MESH.06873458	Due Diligence Growth Opportunity Outline re Project Mulberry Next generation TVT
2/18/2003	ETH.MESH.15363068	ETH.MESH.15363085	Universite de Liege and Ethicon Licensing Agreement

2/20/2003	ETH.MESH.03911107	ETH.MESH.03911108	Arnaud A email chain re TVT complications (an Prof. Häusler)
2/28/2003	ETH.MESH.01222617	ETH.MESH.01222654	Cirelli - Histological evaluation and Comparison of Mechanical Pull Out Strength of Prolene Mesh and Prolene Soft Mesh in a Rabbit Model
3/18/2003	ETH.MESH.00581482	ETH.MESH.00581482	Osoris M email re International Convention Suggestions
3/20/2003	ETH.MESH.04205632	ETH.MESH.04205636	Strategic Plan Challenge
3/26/2003	ETH.MESH03919404	ETH.MESH03919405	Arnaud A email chain re Mulberry
4/10/2003	ETH.MESH.00858110	ETH.MESH.00858111	April 10, 2003 meeting minutes from Project Leader Dan Smith
4/14/2003	ETH.MESH.00260591	ETH.MESH.00260592	Smith,D email chain re Mulberry update
4/30/2003	ETH.MESH.03934952	ETH.MESH.03934967	TVOT Meeting report . . . de Leval, Ruel, Daoud
5/13/2003	ETH.MESH.00030098	ETH.MESH.00030098	Memo from Anthony Powell (VP, Sales) and Marianne Kaminski (Dir. of PE and Relations) to Gynecare
5/15/2003	ETH.MESH.03918552	ETH.MESH.03918553	Emails Brian Luscombe to Axel Arnaud et al. re: De Leval Publication
5/29/2003	ETH.MESH.02222437	ETH.MESH.02222656	DHF 25 1-323 CE Mark of TVT - AA Kit.pdf
5/29/2003	ETH.MESH.00863841	ETH.MESH.00863842	Study spreadsheet
6/6/2003	ETH.MESH.03907853	ETH.MESH.03907854	LeTreguilley L email chain re TVT Serious complication
6/11/2003	ETH.MESH.00764215	ETH.MESH.00764216	Russo-Jankewicz email re Stressful Secrets press release crosses wire
6/19/2003	ETH.MESH.00586018	ETH.MESH.00586019	Eltrasonic Slitting of TVT Mesh presentation
6/20/2003	ETH.MESH.05442881	ETH.MESH.05442883	Leibowitz Tensile Properties, Morphology Test Report
6/24/2003	ETH.MESH.02180737	ETH.MESH.02180737	Toddywala R email re Project Mulberry
6/30/2003	ETH.MESH.05585033	ETH.MESH.05585053	Presentation: Marketing Plan VOC by Boris Batke Project Edelweiss
7/7/2003	ETH.MESH.00030372	ETH.MESH.00030373	Email Brian Luscombe re "Urethral erosion may occur with any sling material" Article (TVT063)

7/9/2003	ETH.MESH.03715978	ETH.MESH.03715980	Email Martin Weisberg to Terry Courtney re TVT question
7/11/2003	ETH.MESH.06884249	ETH.MESH.06884250	Email Brian Luscombe to Steve Bell, et al. re Ulmsten opinion on Mulberry
7/17/2003	ETH.MESH.00865147	ETH.MESH.00865147	Arnaud email re Mulberry IFU
7/18/2003	ETH.MESH.00864085	ETH.MESH.00864087	Email Brian Luscombe to Dan Smith et al. re Design Validation
7/21/2003	ETH.MESH.03919143	ETH.MESH.03919144	Ciarrocca email chain re Gynemesh holding force in tissue
7/21/2003	ETH.MESH.06880021	ETH.MESH.06880023	Email Janice Burns to Dan Smith, et al. RE: Design Validation
7/24/2003	ETH.MESH.00864101	ETH.MESH.00864102	Smith D email chain re TOVT developments
7/25/2003			Patent CA2497158C - Devices for surgical treatment of female urinary incontinence
7/25/2003			Patent WO2004019786A1 - Devices for surgical treatment of female urinary inc
7/25/2003	N/A	N/A	Patent CA2497158C Devices for surgical treatment of female urinary incontinence
7/25/2003	N/A	N/A	Patent WO2004019786A1 - Devices for surgical treatment of female urinary incontinence
8/14/2003	ETH.MESH.01220661	ETH.MESH.01220663	Kammerer G email chain re Aug 11 program
8/15/2003	ETH.MESH.00260739	ETH.MESH.00260744	Email Brian Luscombe re Mulberry Final DRAFT #1
8/18/2003	ETH.MESH.01220693	ETH.MESH.01220697	Kammerer email chain re TVT Mesh Fraying
8/25/2003	ETH.MESH.03715869	ETH.MESH.03715876	Email Martin Weisberg to Dan Smith, et al. re Mulberry Final Draft #1
8/29/2003	N/A	N/A	2003 Marlex MSDS
9/6/2003	ETH.MESH.03738468	ETH.MESH.03738470	Email Martin Weisberg to Marianne Kaminski re TVT Response for Peggy Norton MD
9/8/2003	ETH.MESH.03928696	ETH.MESH.03928697	Arnaud A email chain re TVT complication
10/1/2003	ETH.MESH.14415287	ETH.MESH.14415309	Gynecare TVT AUGS & Competitive Update - copy review submission form

1/1/2004	ETH.MESH.00160813	ETH.MESH.00160821	Only Gynecare TVT Has Long-term Results You Can See
1/7/2004	ETH.MESH.02340829	ETH.MESH.02340901	TVT-O IFU (1/7/2004-3/4/2005)
1/16/2004	ETH.MESH.06164409	ETH.MESH.06164410	Smith D email re Dedications
1/28/2004	N/A	N/A	2004 Marlex MSDS Chevron Phillips
1/29/2004	ETH.MESH.05793690	ETH.MESH.05793693	Gynecare TVT Introduction to cross train the Uterine
2/27/2004	ETH.MESH.00863391	ETH.MESH.00863393	Smith D email chain re 2 TVT Complaints concerning allegedly brittle mesh
3/1/2004	ETH.MESH.00866317	ETH.MESH.00866318	Burns email chain re Mulberry IFU
3/2/2004	ETH.MESH.00865322	ETH.MESH.00865323	Owens C email chain re Reminder on BLUE mesh
3/3/2004	ETH.MESH.14416182	ETH.MESH.14416221	Gynecare Copy Review - Inside Gynecare Vol II, #5
3/10/2004	ETH.MESH.02619601	ETH.MESH.02619616	TVT 20040310 What you Can do about it... TVT-Stress Urinary Incontinence in Women
3/12/2004	N/A	N/A	Sunoco 2004 MSDS
3/12/2004			Sunoco 2004 MSDS
3/17/2004	ETH.MESH.14416076	ETH.MESH.14416081	Gynecare Copy Review Submission Form submitted by Giselle M. Bonett re Gynecare Gynemesh PS
3/29/2004	ETH.MESH.02180759	ETH.MESH.02180761	de Leval J memo
4/14/2004	ETH.MESH.00658058	ETH.MESH.00658065	TVT sales piece (TVT041R3)
4/19/2004	ETH.MESH.00584811	ETH.MESH.00584813	Kammerer G email re Ultrasonic Slitting of Prolene Mesh for TVT
4/19/2004	ETH.MESH.00158286	ETH.MESH.00158288	LIMS Project #: BE-2004-912 Study Report
4/27/2004	ETH.MESH.00862206	ETH.MESH.00862208	LIMS Project #: BE-2004-916
5/4/2004	ETH.MESH.05918776	ETH.MESH.05918776	Schiaparelli J email re Marlex Experience
6/30/2004	ETH.MESH.00863692	ETH.MESH.00863694	Leibowitz email re Comparison of TVT Mesh to Meshes from Competitive Devices
7/21/2004	ETH.MESH.03910799	ETH.MESH.03910800	Arnaud A email chain re TVT Erosion
7/22/2004	ETH.MESH.02201463	ETH.MESH.02201467	Email Walji to Bogardus, et al. re ICS / Paris - Gala Invitee List

8/16/2004	ETH.MESH.05456117	ETH.MESH.05456118	Email James McDivitt to Thomas Barbolt re Autoclaving PROLENE
8/17/2004	ETH.MESH.01814740	ETH.MESH.01814741	Email from Dan Smith to Katrin Elbert re IFU changes
8/18/2004	ETH.MESH.06884516	ETH.MESH.06884517	Mahar K email re Dr. Jensen Follow UP
8/27/2004	ETH.MESH.05795299	ETH.MESH.05795300	Email Marianne Kaminski to Amy Vie, et al. re 2004 budget - PE August adjustments
9/7/2004	ETH.MESH.00681364	ETH.MESH.00681366	Walji email chain re Pelvic Floor Monthly - August Report - Next Gen Materials Progress
9/11/2004	ETH.MESH.08107153	ETH.MESH.08107155	Gynecare University Program Las Vegas, Nevada
9/23/2004	ETH.MESH.03624321	ETH.MESH.03624322	"Professional Education for GYNECARE TVT Physician Training" updated draft by Marianne Kaminski
9/24/2004	ETH.MESH.05795309	ETH.MESH.05795315	Gynecare Mega Course Uterine Health Urodynamics Incontinence and Pelvic Floor Repair and the OB/GYN Surgeon, Urogynecologist and Urologist
10/7/2004	ETH.MESH.00031538	ETH.MESH.00031560	Sales School Presentation: Gynecare Professional Relations and Professional Education "Educating Customers Worldwide to improve the lives of women!"
11/1/2004	ETH.MESH.05548122	ETH.MESH.05548123	Smith D email re Update from Oct 27 cadaver lab
11/2/2004	ETH.MESH.01813975	ETH.MESH.01813978	Email from Patty Lancos to Manuel Castro and Dan Smith re FDA Prep
11/5/2004	ETH.MESH.03589219	ETH.MESH.03589220	MedWatch Report
12/6/2004	ETH.MESH.01217673	ETH.MESH.01217690	Development Contract TVT-Next (TVTx)
12/8/2004	ETH.MESH.08003197	ETH.MESH.08003212	TVT 20041208 Gynecare TVT Tension-free Support for Incontinence Patient Brochure reprint /Robin Osman
1/3/2005	ETH.MESH.05768705	ETH.MESH.05768712	2005 Variable Compensation Plan Sales Representative

1/5/2005	ETH.MESH.00440005	ETH.MESH.00440007	Email Laura Angelini to Ronnie Toddywala, et al. re Important Laser cut mesh Update
1/17/2005	ETH.MESH.00585220	ETH.MESH.00585220	Kammerer email re Presentation #1
1/18/2005	ETH.MESH.07931874	ETH.MESH.07931886	Hojnoski Personnel File
1/19/2005	ETH.MESH.02248778	ETH.MESH.02248778	Presentation: Mechanical vs. "Machine"-cut Mesh
1/19/2005			Mechanical v "Machine" - cut Mesh Prepared by Allison London Brown, Gene Kammerer
1/27/2005	N/A	N/A	United States Patent Application Publication De Leval US20050021086 20050127
1/27/2005	ETH.MESH.05553782	ETH.MESH.05553782	Smith email re TVT-U
1/27/2005			US Patent Application Publication US20050021086 20050127
1/28/2005	ETH.MESH.08792936	ETH.MESH.08792938	Carino email chain re Recommendations for Non-Sales and Marketing Glamour Trip Award
1/30/2005	ETH.MESH.11474337	ETH.MESH.11474337	Castillo email chain re Oscar -- The latest fiasco
2/1/2005	ETH.MESH.00524907	ETH.MESH.00524907	Presentation: TVT Bonnie Blair Campaign
2/2/2005	ETH.MESH.00162420	ETH.MESH.00162421	TVT Mailers for Physicians
2/2/2005	ETH.MESH.14410478	ETH.MESH.14410484	McCabe Gynecare TVT Mesh Brochure copy review submission form
2/11/2005	ETH.MESH.02340471	ETH.MESH.02340503	TVT IFU through
2/16/2005	ETH.MESH.14409737	ETH.MESH.14409741	Copy review submission form - Hernia ad; Proceed Mesh. ULTRAPRO mesh and PROLENE hernia system
2/28/2005	ETH-03531	ETH-03567	Everett J Summary Memo for Revision C of the Gynecare PROLIFT Device Design Safety Assessment
3/1/2005	ETH.MESH.03574916	ETH.MESH.03574919	Email Charlotte Owens to Carol Holloway re Medical Review file #30005136
3/10/2005	ETH.MESH.03499528	ETH.MESH.03499529	Berger L Itt Wallingford J re Unknown TVT Ref #3005146
3/10/2005	ETH.MESH.05245427	ETH.MESH.05245428	Next Generation Mesh Discussion



3/15/2005	HMESH_ETH_01876389	HMESH_ETH_01876393	Oldelehr M email chain re Kalamazoo TVT Business at Risk
3/24/2005	ETH.MESH.06828907	ETH.MESH.06828909	Hunsicker email chain re ICS Submission
4/5/2005	ETH.MESH.03575061	ETH.MESH.03575061	Email Charlotte Owens to Carin Rassier re Complaint 30005255
4/12/2005	ETH.MESH.03915588	ETH.MESH.03915590	Kammerer, G email chain re Ultrapro
4/13/2005	ETH.MESH.00994917	ETH.MESH.00994918	Barbara McCabe email re Sheath Sales Tool
4/13/2005	ETH.MESH.02026591	ETH.MESH.02026595	Sunco C4001 Polypropylene Homopolymer MSDS
4/13/2005	ETH.MESH.00658421	ETH.MESH.00658429	TVT 20040413 Gynecare TVT Tension-free Support for Incontinence Patient Education Brochure/Robin Osman
4/13/2005	ETH.MESH.05469908	ETH.MESH.05469912	Barbolt, T email chain re Ultrapro
4/13/2005	ETH.MESH.05795322	ETH.MESH.05795324	Emails Marianne Kaminski to Paul Parisi, et al. re Q1 PE results REVISED
4/13/2005	ETH.MESH.02614599	ETH.MESH.02614603	Corporate Product Characterization Protocol to Evaluate Elongation, Particle Loss and Flexural Rigidity of TVT U PROLENE Mesh Laser-Cut vs Mechanical-Cut Version 1
4/13/2005	ETH.MESH.04020134	ETH.MESH.04020137	Holste, J email chain re Ultrapro
4/14/2005	ETH.MESH.03915567	ETH.MESH.03915572	Toddywala, R email chain re Ultrapro
4/29/2005	ETH.MESH.05549696	ETH.MESH.05549700	Komamycky P email chain re Bio compatibility samples
5/5/2005	ETH.MESH.06696367	ETH.MESH.06696379	Seppa K Memo re Performance Evaluation of TVT U Prolene Mesh: Mechanical Cut versus Laser Cut STudy (LIMS#BE-2005-1920) Version 3
5/6/2005	ETH.MESH.00526473	ETH.MESH.00526474	London Brown A email re Laser-cut Mesh
5/25/2005	ETH.MESH.02627466	ETH.MESH.02627466	TVT Retropubic Issue Report No. 30005181
6/1/2005	ETH.MESH.08107933	ETH.MESH.08107933	Oldelehr email re gynecology vs urology



6/3/2005			Labelling for Medical Devices by SG1 and endorsed by The Global Harmonization Task Force
6/6/2005	ETH.MESH.02020712	ETH.MESH.02020713	Zaddem V email chain re MINT: 6/2/05 Materials Advisory meeting minutes
6/28/2005	ETH.MESH.19356913	ETH.MESH.19356915	Objectives for Jennifer - May-August
7/19/2005	ETH.MESH.00412260	ETH.MESH.00412269	Clinical Study Agreement between Dr. Douglas Grier and Ethicon
8/16/2005	ETH.MESH.00525573	ETH.MESH.00525573	London Brown A email re TVT Laser Cut Mesh
8/23/2005	ETH.MESH.04985249	ETH.MESH.04985252	Email Paula Evans to Sungyoon Rha et al. re TVT Laser Cut Value Proposition and Forecast
8/24/2005	ETH.MESH.00525322	ETH.MESH.00525400	Gynecare TVT Professional Education Slides
8/29/2005	ETH.MESH.12933182	ETH.MESH.12933183	Physician form letter
9/1/2005	ETH.MESH.03605398	ETH.MESH.03605402	Consulting Agreement B-1 between Brian J. Flynn and Ethicon
11/4/2005	ETH.MESH.09268506	ETH.MESH.09268508	Rousseau, R email chain re Gynemesh PS w/Monocryl
1/15/2006	ETH.MESH.00134498	ETH.MESH.00134499	Miller email chain re GYNECARE TVT Latest Complication Data
1/15/2006	ETH.MESH.00756887	ETH.MESH.00756888	Email Dennis Miller to Dharini Amin et al. re Gynecare TVT Latest Complication Data
1/19/2006	ETH.MESH.03908029	ETH.MESH.03908031	Van Dijk email chain re Ti-mesh research
1/20/2006	ETH.MESH.1218594	ETH.MESH.1218596	London Brown email chain re TVT U Completion Report Version 3
1/26/2006	ETHMESH.OHARA.00000315	ETHMESH.OHARA.00000321	Vandenburgh 2005 Performance and Development Plan Summary for Christopher O'Hara
1/31/2006	ETH.MESH.03911712	ETH.MESH.03911715	Arnaud A email chain re TVT - TVT-O Specifications
2/1/2006	ETH.MESH.00394544	ETH.MESH.00394553	Global Regulatory Strategy GYNECARE TVT - Laser Cutting Project
2/6/2006	ETH.MESH.00847536	ETH.MESH.00847536	Robinson email chain re TVT complications

2/15/2006	ETH.MESH.00584291	ETH.MESH.00584292	Flatow J email chain re DVer protocol for particle loss
2/20/2006	ETH.MESH.03929173	ETH.MESH.03929177	Arnaud email chain re TVM discussions
2/23/2006	ETH.MESH.00302390	ETH.MESH.00302392	Memo Dan Lamont re TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk
2/23/2006	ETH.MESH.00330760	ETH.MESH.00330764	Email Cindy Crosby to Mark Yale, et al. re MHRA request - TVT blue pigment risk assessment
2/24/2006	ETH.MESH.00302105	ETH.MESH.00302106	Lamont D Memo re TVT Laser Cut Mesh Risk Analysis Summary
2/24/2006	ETH.MESH.10984358	ETH.MESH.10984359	Lamont D Memo re TVT Laser Cut Mesh (LCM) Risk Analysis Summary
2/28/2006	ETH.MESH.00846523	ETH.MESH.00846523	Robinson email re tvt - training
3/1/2006	ETH.MESH.00134029	ETH.MESH.00134031	Mahar email chain re Urgent Request: Revised TVt Complication data 2-9-06
3/2/2006	ETH.MESH.04122262	ETH.MESH.04122264	Email Dr. James Hart to David Robinson re tvt o training
3/6/2006	ETH.MESH.01222075	ETH.MESH.01222079	Kammerer memo re Elongation Characteristics of Laser Cut PROLENE Mesh for TVT
3/6/2006	ETH.MESH.03358398	ETH.MESH.03358402	Kammerer G Memo to Weisbert and Robinson re Elongation Characteristics of Laser Cut PROLENE Mesh for TVR
3/7/2006	ETH.MESH.01784823	ETH.MESH.01784828	Clinical Expert Report for Laser Cut Mesh signed by Martin Weisberg, MD and David Robinson MD
3/7/2006	ETH.MESH.01221735	ETH.MESH.01221740	Weisberg, Robinson Clinical Expert Report
3/9/2006	ETH.MESH.01221618	ETH.MESH.01221619	Kammerer G email chain re Elongation properties of LCM
3/10/2006	ETH.MESH.11920108	ETH.MESH.11920110	Urology University March 10-11, 2006
3/10/2006	ETH.MESH.00585672	ETH.MESH.00585673	Next Generation Mesh Discussion Agenda
3/13/2006	ETH.MESH.05446127	ETH.MESH.05446128	Holste J email chair re Mesh and Tissue Contraction in Animal

3/20/2006	ETH.MESH.01219984	ETH.MESH.01219994	Flatow Completion Report for Design Verification of TVT Laser Cut Mesh
3/22/2006	ETH.MESH.00169748	ETH.MESH.00169751	TVT Slim Jim (TVT107)
3/29/2006	ETH.MESH.00302181	ETH.MESH.00302184	Email Daniel Lamont to Jacqueline Flatow re TVT LCM - design inputs
3/30/2006	ETH.MESH.01945854	ETH.MESH.01945854	Email Mark Yale re TVT laser cut equivalency
3/30/2006	ETH.MESH.00700348	ETH.MESH.00700350	Gadot email chain re Laser Cut Mesh Positioning (Redacted)
4/2/2006	ETH.MESH.06040171	ETH.MESH.06040173	Mahar K email chain re Laser Cut Mesh Positioning
4/7/2006	ETH.MESH.05222673	ETH.MESH.05222705	TVT IFU through
4/17/2006	ETH.MESH.14450438	ETH.MESH.14450442	Kammerer G Memo re Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT Laser Cut Mesh
4/18/2006	ETH.MESH.00998349	ETH.MESH.00998355	Weisberg M and Robinson D CER
4/18/2006	ETH.MESH.00167104	ETH.MESH.00167110	CER Weisberg - Laser Cut Mesh
4/25/2006	ETH.MESH.06696589	ETH.MESH.06696592	Minute - Tactile appraisal of TVT LCM & LCM-MC both vs MCM
4/26/2006	ETH.MESH.10302266	ETH.MESH.10302267	Damotte email chain re Laser cut TVT - Surgeon's Preference Evaluation
5/1/2006	ETH.MESH.03358217	ETH.MESH.03358224	Kammerer G email chain re French Standard on TVT & Meshes (Comments required)
5/4/2006	ETH.MESH.01221024	ETH.MESH.01221025	Kammerer G email re New Standards for Urethral Slings
5/9/2006	ETH.MESH.01816990	ETH.MESH.01816990	Mesh development timeline
5/9/2006	ETH.MESH.00585802	ETH.MESH.00585802	Kammerer G email re Particle loss of TVT
5/9/2006	ETH.MESH.01219629	ETH.MESH.01219630	Flatow J email chair re Particle loss on TVT
5/22/2006	ETH.MESH.00584175	ETH.MESH.00584178	Sungyoon Rha email re First Human Use - Surgeon preference Questionnaire
5/22/2006	HMESH_ETH_01840151	HMESH_ETH_01840152	"World Premiere" as Ethicon Women's Health & Urology with special guest Bonnie Blair

5/31/2006	ETH.MESH.04321670	ETH.MESH.04321681	Visual Acceptance Criteria for Blister Sealing; VSE0007, Revision: D
6/2/2006	ETH.MESH.00870466	ETH.MESH.00870476	Expert Meeting Minutes - Meshes for Pelvic Floor Repair
6/12/2006	ETH.MESH.00585842	ETH.MESH.00585843	Kammerer G email chain re TVT LCM - particle loss (reimbursement submission)
6/13/2006			T 213 om-01 Proposed Revision - Dirt in pulp - chart method
6/14/2006	ETH.MESH.03274663	ETH.MESH.03274670	Email Marie-Ange Damotte to Sungyoon Rha, et al. re TVT Laser Cut First Human Use - surgeon preference questionnaire
6/15/2006	ETH.MESH.08164248	ETH.MESH.08164256	Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Materials for Medical Devices
6/22/2006	ETH.MESH.00998347	ETH.MESH.00998347	Gadot, Harel email re LCM - Launch Strategy EMEA
6/22/2006			Gadot, H EMEA Launch Strategy
6/23/2006	ETH.MESH.00526484	ETH.MESH.00526487	St. Hilaire P email chain re LCM - Launch Strategy EMEA
6/26/2006	ETH.MESH.00167119	ETH.MESH.00167119	Product Pointer: Gynecare TVT Tension-free Support for Incontinence -- available in laser cut mesh
6/27/2006	ETH.MESH.00585823	ETH.MESH.00585832	Kammerer email chain re URGENTFrench STANDARD ON TVT & Meshes
7/17/2006	ETH.MESH.08003215	ETH.MESH.08003230	TVT 20060717 Patient Brochure - Find out how to stop urine leakage like Bonnie did
7/20/2006	ETH.MESH.00311802	ETH.MESH.00311804	Email Paula Evans to David Robinson et al. re TVT dataMcNelis, Linda
8/1/2006	ETH.MESH.05454207	ETH.MESH.05454207	Jürgen email re Fotos cadeavar lab
8/13/2006	ETH.MESH.00870481	ETH.MESH.00870482	London Brown, A email chainre LIGHTning clinical strategy
8/28/2006	ETH.MESH.06001408	ETH.MESH.06001408	ICM Project Presentation

8/29/2006	ETH.MESH.00584527	ETH.MESH.00584527	Second half photo presentation. ppt
9/27/2006	ETH.MESH.08003231	ETH.MESH.08003246	TVT016R6 Patient brochure - Find out how to stop urine leakage like Bonnie did
10/4/2006	ETH.MESH.00746204	ETH.MESH.00746208	Hernandez J email re TVT LCM Early EU Feedback
10/9/2006	ETH.MESH.00524059	ETH.MESH.00524060	Email Cheryl Bogardus to Dharini Amin re TVT 10 year anniversary/10 year data from Nillson
1/2/2007	ETH.MESH.00161512	ETH.MESH.00161513	TVT sales piece (TVTS004)
1/23/2007	ETHMESH.OHARA.00000322	ETHMESH.OHARA.00000327	Qually 2006 Performance and Development Plan Summary for O'Hara
2/6/2007	ETH.MESH.00722339	ETH.MESH.00722349	St. Hilaire email chain re OBGYN Department Members. Due to the potential serious implications . . .
2/6/2007	ETH.MESH.00719198	ETH.MESH.00719209	Mahar email chain re hospital concern from medico-legal standpoint
2/7/2007	ETH.MESH.02316434	ETH.MESH.02316436	Robinson email chain re PLEASE DO NOT DISTRIBUTE THIE EMAIL!!! . . .broadcast bulletin re Dr. Levy
2/9/2007	ETH.MESH.05475773	ETH.MESH.05475822	Presentation: The (clinical) argument of lightweight mesh in abdominal surgery by Boris Batke
2/20/2007	ETH.MESH.00303084	ETH.MESH.00303085	Lamont D email chain re Complaint Summaries
2/23/2007	ETH.MESH.02017152	ETH.MESH.02017158	Ethicon Expert Meeting: Meshes for Pelvic Floor Repair brochure
2/23/2007	ETH.MESH.01782867	ETH.MESH.01782867	Factors Related to Mesh Shrinkage: What do we know? A review of literature and internal studies
3/20/2007	ETH.MESH.00539862	ETH.MESH.00539898	TVT-World-Wide Observational Registry for Long-Term Data
4/5/2007	ETH.MESH.01218361	ETH.MESH.01218367	Spychaj K memo re Shrinking meshes
4/17/2007	N/A	N/A	United States Patent De Leval US7204802
4/17/2007			US7204802 - US Patent De Leval

5/4/2007	HMESH_ETH_06509815	HMESH_ETH_06509817	Timmer message re updated Mesh Shrinkage Discussion meeting w/attachments
5/11/2007	ETH.MESH.00136359	ETH.MESH.00136359	Email Price St. Hilaire to Dr Kavalier re AUA in Booth Activities
5/31/2007	ETH.MESH.08003263	ETH.MESH.08003278	Marketing Brochure - One day you have urine leakage. The next day you don't. End of Story.
6/1/2007	ETH.MESH.03913651	ETH.MESH.03913665	CDMA Eurpoe Meeting Urinary Incontinence Platform minutes June 1, 2007
7/6/2007	ETH.MESH.05447475	ETH.MESH.05447476	Engel D email chain re How inert is polypropylene?
7/6/2007	ETH.MESH.05447481	ETH.MESH.05447482	Barbolt email chain re How inert is polypropylene
7/9/2007	ETH.MESH.05588123	ETH.MESH.05588126	Wohlert S email chain re How inert is polypropylene?
7/20/2007	ETH.MESH.05920616	ETH.MESH.05920617	Chomiak M email re Defining light weight mesh
8/31/2007	ETH.MESH.00844341	ETH.MESH.00844344	Robinson D email Chain re Asking TVT Complication? - Fraying
9/24/2007	ETH.MESH.06214296	ETH.MESH.06214300	EPC131 Revision A Neuchatel Prolift+M Product Specification
9/27/2007	ETH.MESH.02114101	ETH.MESH.02114103	Osman email chain re Wal-Mart Female Pelvic Health Poster Options
10/5/2007	ETH.MESH.06372356	ETH.MESH.06372363	Global Harms List Document for Review & Comment by Medical Affairs Personnel
10/9/2007	N/A	N/A	2007 Marlex MSDS
11/1/2007	N/A	N/A	FDA Science and Mission at Risk -- Report from Subcommittee on Science and Technology
1/8/2008	ETH.MESH.03509909	ETH.MESH.03509910	Flores email chain re New complaint acknowledgement/request for info 10100062684
1/9/2008	ETH.MESH.04127133	ETH.MESH.04127134	Maree, A email chain re TGA Meeting
2/4/2008	ETHMESH.OHARA.00000328	ETHMESH.OHARA.00000333	Ullmann 2007 Performance and Development Plan Summary for O'Hara
2/7/2008	ETH.MESH.16416002	ETH.MESH.16416004	Kahlson H email chain re Conversion to Laset Cut TVT

2/8/2008	ETH.MESH.08692660	ETH.MESH.08692667	Master Consulting Agreement between Ethicon (signed by Price St. Hilaire) and Carl Nilsson
2/19/2008	ETH.MESH.00057336	ETH.MESH.00057374	Pelvic Floor Summit
2/22/2008	ETH.MESH.01775242	ETH.MESH.01775257	Executive Summary - Preliminary results of peri-operative and 3-month outcomes from a world-wide observational registry of tension-free vaginal tapes in with with SUI
3/3/2008	ETH.MESH.01279975	ETH.MESH.01279976	Gadot H email re Next step in SUI sling
3/3/2008	ETH.MESH.00328895	ETH.MESH.00328901	Robinson D email chain re Quality issue with a batch of gynemesh
3/4/2008	ETH.MESH.02293673	ETH.MESH.02293677	Gadot H email chain re Next step in SUI Sling
3/5/2008	ETH.MESH.00303944	ETH.MESH.00303945	Lamont D email chain re Gynemesh issue
3/19/2008	ETH.MESH.03614158	ETH.MESH.03614158	Email Kyung Yu to Susie Chilcoat re Flynn preceptorships
3/26/2008	ETH.MESH.03458123	ETH.MESH.03458138	Bonnie Blair - Find out how to stop uring leakage like Bonnie did
4/15/2008	ETH.MESH.03916716	ETH.MESH.03916727	Notes
4/15/2008	ETH.MESH.02090196	ETH.MESH.02090209	Trip Notes
4/15/2008	ETH.MESH.09909642	ETH.MESH.09909655	Trip Notes
4/15/2008	ETH.MESH.15433760	ETH.MESH.15433773	Trip Notes
4/16/2008	ETH.MESH.10003595	ETH.MESH.10003603	Notes - Post Mini TVT Procedure Discussion
4/23/2008	ETH.MESH.03916715	ETH.MESH.03916715	Hernandez email chain re Liege Trip Notes. doc
4/29/2008	ETH.MESH.00304013	ETH.MESH.00304014	Lamont D email chain re Post Launch Reviews
5/5/2008	ETH.MESH.03914629	ETH.MESH.03914630	Arnaud email chain re sling business for SUI
5/16/2008	ETH.MESH.00345289	ETH.MESH.00345291	Email Krystina Laguna to Price St. Hilaire re Copy Review TVT Complications
6/4/2008	ETH.MESH.00057335	ETH.MESH.00057335	Linton email re AUGS attendees
6/6/2008	ETH.MESH.00355003	ETH.MESH.00355007	Nilsson, et al. "Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence"
6/18/2008	ETH.MESH.04048515	ETH.MESH.04048520	Carl G. Nilsson KOL Interview



7/29/2008	ETH.MESH.09004550	ETH.MESH.09004553	Kadadkia R email chain re TVT LCM - launch delay due to OQ failure
8/14/2008	ETH.MESH.03459088	ETH.MESH.03459104	TVT Brochure "The Choice to End Stress Urinary Incontinence. Find out how to stop urine leakage like Bonnie did"
8/27/2008	ETH.MESH.09504568	ETH.MESH.09504571	Scavona email chain re PQI TVT S
8/27/2008	ETH.MESH.09504558	ETH.MESH.09504559	Brennan email chain re TVT-S Mesh Torn Complaint Review for Wednesday morning Conf Call
9/5/2008	ETH.MESH.03459211	ETH.MESH.03459212	FOR IMMEDIATE RELEASE: New Study Offers More Than a Decade of Evidence for Minimally-Invasive Surgery to Treat Female Incontinence
9/24/2008	ETH.MESH.04099233	ETH.MESH.04099234	Email Melissa Day to Meng Chen, et al. re #10100078150
9/24/2008	ETH.MESH.19354118	ETH.MESH.19354119	Email Marcus Oldelehr to Brian Flynn re Flynn visit 10/23
9/25/2008	ETH.MESH.03914909	ETH.MESH.03914909	Arnaud A email re TVT World registry
9/25/2008	ETH.MESH.00164643	ETH.MESH.00164648	TVT sales piece
12/4/2008	N/A	N/A	2008 Marlex MSDS
12/9/2008	ETH.MESH.01673341	ETH.MESH.01673341	Presentation: "Stop Coping. Start Living. Treatment Options for Urinary Incontinence."
1/1/2009	ETHMESH.OHARA.00000340	ETHMESH.OHARA.00000346	2009 Performance and Development Plan Summary for Christopher O'Hara
1/7/2009	ETH.MESH.01202101	ETH.MESH.01202103	Kirkemo A email chain re My revised writeup of the DeLeval and Waltregny Visit
1/7/2009	ETH.MESH.03916905	ETH.MESH.03916913	Hinoul P email chain re My revised writeup of the DeLeval and Waltregny visit
1/7/2009	ETH.MESH.09955474	ETH.MESH.09955479	Total Petrochemicals Certificate N° 9
1/23/2009	ETH.MESH.04050265	ETH.MESH.04050267	Hinoul memo re meeting with Prof DeLeval and Prof Waltregny
1/26/2009	ETH.MESH.11985160	ETH.MESH.11985164	Issue Report



1/28/2009	ETH.MESH.07181044	ETH.MESH.07181044	Urquhart email re TVT World AE Report w/attachment
1/28/2009	ETH.MESH.03208548	ETH.MESH.03208549	Hinoul P email chain re TVT World AE Report
1/29/2009	ETH.MESH.04094863	ETH.MESH.04094864	Emails Bryan List to Meng Chen et al. re TVT IFUs on tape extrusion, exposure and erosion
1/29/2009	ETH.MESH.04093125	ETH.MESH.04093125	Chen M email re TVT IFUs on tape extrusion, exposure and erosion
2/6/2009	ETH.MESH.00007091	ETH.MESH.00007091	Haby email re CR Approved 2009-98
2/16/2009	N/A	N/A	IUGA 2009 Ital Sponsorship Invoice - 34th Annual Meeting Como, Italy June 10-20, 2009
2/23/2009	ETH.MESH.07383730	ETH.MESH.07383731	Zipfel R email chain re Ultrapro mesh info
2/25/2009	ETH.MESH.03208738	ETH.MESH.03208738	Email Jason Hernandez re Quick Response Needed to Finalize TVT WORLD Recommendation for Board Meeting on Monday Mar 2nd
2/27/2009	ETH.MESH.09951746	ETH.MESH.09951747	Ciarrocca email chain re MiniMe discussion at the board meeting
3/2/2009	ETH.MESH.00827376	ETH.MESH.00827379	Hernandez J email chain re EWHU Board recommendation
3/6/2009	ETH.MESH.09951087	ETH.MESH.09951090	Ciarrocca email re Sling thoughts and next steps 11-13-08.doc
3/6/2009	ETH.MESH.03966039	ETH.MESH.03966040	Emails Scott Finley to Melissa Chaves re Fast Break Update
3/9/2009	ETHMESH.OHARA.00000334	ETHMESH.OHARA.00000339	Ullmann 2008 Performance and Developmnet Plan Summary for Christopher O'Hara
3/11/2009	ETH.MESH.00339053	ETH.MESH.00339057	Physican brochure/sales aid "Make Data and Safety your Choice"
3/11/2009	ETH.MESH.00590896	ETH.MESH.00590897	Hinoul P email re EJOGTB-08-4159R1 - Minor Revision
3/19/2009	ETH.MESH.06040657	ETH.MESH.06040658	Mahar email chain re Credo debrief
3/20/2009	ETH.MESH.00407285	ETH.MESH.00407285	Letter Patricia Beach (Ethicon) to Dr. Douglas Grier re TVT World Registry

4/1/2009	ETH.MESH.00346227	ETH.MESH.00346227	Lisa B email re TVT-Mini clinical support
4/8/2009	ETH.MESH.00591127	ETH.MESH.00591128	Hinoult email chain re registry for all!
4/8/2009	ETH.MESH.05238373	ETH.MESH.05238374	Hinoult email chain re Tensile Properties of POP Mesh
4/9/2009	ETH.MESH.05238382	ETH.MESH.05238384	Jones, S email re Tensile Properties of POP Mesh
4/20/2009	ETH.MESH.01238552	ETH.MESH.01238553	Piet Hinoult letter re meeting with Prof deLeval and Prof Waltregny
4/22/2009	ETH.MESH.01238538	ETH.MESH.01238541	Email Piet Hinoult to Dan Smith re Meeting Minutes Prof deLeval 20/04/09
4/22/2009	ETH.MESH.03917298	ETH.MESH.03917300	Email Piet Hinoult to Katrin Elbert et al. re Meeting Minutes Prof deLeval 20/04/09
4/22/2009	ETH.MESH.01238551	ETH.MESH.01238551	Email Piet Hinoult to Katrin Elbert et al. re Meeting Minutes Prof deLeval 20/04/09
4/24/2009	ETH.MESH.03259439	ETH.MESH.03259440	Email Judi Gauld to Colin Urquhart re green journal
4/28/2009	ETH.MESH.00533250	ETH.MESH.00533256	TVT-World-Wide Observational Registry for Long-Term Data
4/30/2009	ETH.MESH.06928168	ETH.MESH.06928168	Email Henri Decloux to Valerie Emperado re T-Con follow up
5/15/2009	ETH.MESH.09957926	ETH.MESH.09957927	Email Katrin Elbert to Henri Decloux re Last week's Medi-Line visit
5/20/2009	ETH.MESH.15285672	ETH.MESH.15285672	Email Stale Kvitle to Jean DeLeval, et al. re Mini Me follow up from our visit
5/26/2009	ETH.MESH.02122903	ETH.MESH.02122905	Brennan email chain re TVT Complications Statement 2008
5/26/2009	ETH.MESH.06806078	ETH.MESH.06806092	F 2097 - 08 Standard Guide for Packaging of Medical Products
5/26/2009	ETH.MESH.02250914	ETH.MESH.02250945	All Active CAPA's
6/3/2009	ETH.MESH.04314739	ETH.MESH.04314740	Chaves email re Fast Break Promotion Update
6/11/2009	ETH.MESH.14442958	ETH.MESH.14442976	Divilio Memo re The Use of Mesh in Hernia Repair
6/19/2009	ETH.MESH.10630809	ETH.MESH.10630813	Sunoco MSDS 2009

6/26/2009	ETH.MESH.08007248	ETH.MESH.08007249	Email Brian Flynn to Jonathan Fernandez re Contracted Pricing
6/29/2009	ETH.MESH.07402878	ETH.MESH.07402879	Email Michelle Hurley to Jackie Sauer re SBT Meeting
7/1/2009	ETH.MESH.00139845	ETH.MESH.00139867	AdvaMed Code of Ethics on Interactions with Healthcare Professionals
7/15/2009	ETH.MESH.10133116	ETH.MESH.10133116	Email Brian Langen to Vincenza Zaddem re Plus-M payment for Mel Anhalt
7/16/2009	ETH.MESH.01239065	ETH.MESH.01239066	Robinson D email chain re TVT RR IFU Version 5 071409_T-3466
7/28/2009	ETH.MESH.06239100	ETH.MESH.06239108	Bobertz email chain re URGENT: Resin information request
7/30/2009	ETH.MESH.03656697	ETH.MESH.03656699	Email Takahito Hino to Patrice Napoda re TVT Japanese Package Insert
8/1/2009	ETH.MESH.10233144	ETH.MESH.10233148	2009 Field Visit Letter
8/7/2009	ETH.MESH.09958050	ETH.MESH.09958051	Email Henri Decloux to Severine Timoner Fortin re Quote for sample production
8/7/2009	ETH.MESH.09951106	ETH.MESH.09951107	Email Severine Timoner Fortin to Valerie Emperado et al. re For Information - lot of TVT used for Deleval's tests
8/8/2009	ETH.MESH.09954485	ETH.MESH.09954486	Hinoul email chain re For Information - lot of TVT used for Deleval's tests
8/12/2009			US Patent Application Publication De Leval US20090306459
8/12/2009	N/A	N/A	United States Patent Application Publication De Leval US20090306459
8/17/2009	ETH.MESH.10227358	ETH.MESH.10227359	Prine email chain re TVT promotion Slam Dunk Winners
8/21/2009	ETH.MESH.02596464	ETH.MESH.02596467	Email David Waltregny to Piet Hinoul re TR: For Information - lot of TVT used for Deleval's tests
8/27/2009	ETH.MESH.09955464	ETH.MESH.09955464	Timoner Fortin email re Mini-O Raw material proposed by Suppliers for button aid

9/14/2009	ETH.MESH.00592915	ETH.MESH.00592916	Savidge S email chain re TVT RR IFU 090911b_T-3467
9/17/2009	ETH.MESH.03722384	ETH.MESH.03722386	Email Paul DeCosta to Thomas Divilio, et al. re: Mesh + Anti-proliferative agent
9/28/2009	ETH.MESH.03618587	ETH.MESH.03618596	Master Consulting Agreement between Brian J. Flynn and Ethicon
9/29/2009	ETH.MESH.00533283	ETH.MESH.00533286	Communication Plan to close TVT World Registry
11/3/2009			United States Patent De Leval US7611454
11/3/2009	N/A	N/A	United States Patent De Leval US7611454
1/4/2010	ETH.MESH.03832685	ETH.MESH.03832692	Monthly Closed CAPA
1/5/2010	ETH.MESH.00077727	ETH.MESH.00077732	Timoner Fortin, S email chain re Prosima learning's at preceptor sites EMEA
1/8/2010	ETH.MESH.00340990	ETH.MESH.00340999	Global Regulatory Strategy for TVT IFU (RMC P15506/E) Update (Part II, RA0001-2010, Rev. 0) by Susan Lin to John Young
1/17/2010	ETH.MESH.01785259	ETH.MESH.01785260	Hinoul, P email chain re +M relaxation
1/21/2010	ETH.MESH.09234953	ETH.MESH.09234954	TVT Matketing email re 2010 Planning -- "Voice of the Customer" feedback
1/27/2010	ETH.MESH.00349508	ETH.MESH.00349512	TVT ad "Demand the most proven technology when selecting a mid-urethral sling... Make DATA and SAFETY YOUR CHOICE"
1/28/2010	ETH.MESH.09234951	ETH.MESH.09234952	Flores email chain re Continence Health Brand Team - TVT Feedback
2/6/2010	ETH.MESH.01805963	ETH.MESH.01805963	Peebles R email re Mesh slides for NTM
2/16/2010	ETH.MESH.09235084	ETH.MESH.09235085	Toglia M email chain re Ethicon Women's Health and Urology National Training meeting - TVT
2/17/2010	ETH.MESH.00340839	ETH.MESH.00340839	Gynecare TVT Device Instructions for Use Revision Design Verification Memo by Kirkemo, Robinson and Hinoul
2/19/2010	ETH.MESH.02254087	ETH.MESH.02254087	Beath C email re clinical data
2/24/2010	ETH.MESH.08014324	ETH.MESH.08014327	Email Jonathan Fernandez to Carol Padgett re Dr. Alvina Driscoll

2/25/2010	ETH.MESH.00073089	ETH.MESH.00073093	Robinson D email chain re 510k submission and clearance
2/26/2010	ETH.MESH.00659430	ETH.MESH.00659431	Physician brochure/sales aid
2/27/2010	ETH.MESH.09214438	ETH.MESH.09214438	Peebles email re participation next week - copy-approved slides
3/4/2010	ETH.MESH.16263696	ETH.MESH.16263715	EWHU 2009 Awards Ceremony
3/10/2010	ETH.MESH.00074068	ETH.MESH.00074070	Savidge S and Johnson L - biocompatiblity statement
3/17/2010	ETH.MESH.19306944	ETH.MESH.19306946	Ullman email chain re "Take Back Share" - Feb Update
3/19/2010	ETH.MESH.01201387	ETH.MESH.01201389	Bryan L email chain re EBM Sub-team meetings for EWHU
3/23/2010	ETH.MESH.00351439	ETH.MESH.00351441	Smith D email chain re Input to the one-pager to BR
3/24/2010	ETH.MESH.09932848	ETH.MESH.09932849	Iacobone email chain re Stability Testing
3/25/2010	ETH.MESH.02013947	ETH.MESH.02013948	Zaddem V email chain re Your input on 30 in 3 and Speed to launch
3/25/2010	ETH.MESH.00212665	ETH.MESH.00212665	Draft TVT Family strategic positioning overview presentation
4/6/2010	ETH.MESH.10632641	ETH.MESH.10632644	Elbert K email chain re CO-0022344 for your review; Target Approval 4-12-2010 12:00:00 AM EDT
4/6/2010	ETH.MESH.11205022	ETH.MESH.11205027	Email Katrin Elbert to Sheelu Samuel re FW: CO-0022344 for your review; Target Approval 04-12-2010 12:00:00 AM EDT
4/6/2010	ETH.MESH.14819286	ETH.MESH.14819290	Taggart D email chain re CO-002344 for your review: Target Approval 04-12-2010 12:00 AM EDT
4/6/2010	ETHMESH.CHAHAL.00000006	ETHMESH.CHAHAL.00000027	Chahal Employee Secrecy, Intellectual Property, Non-Competition and Non-Solicitation Agreement
4/7/2010	ETH.MESH.00602025	ETH.MESH.00602027	Robinson D email re Please hold: database study vendor selection

4/9/2010	ETH.MESH.05620358	ETH.MESH.05620362	NCR Summary Report NCR10-01914
4/13/2010	ETH.MESH.09656790	ETH.MESH.09656795	Trzewik J email chain re laser cutting
4/14/2010	ETH.MESH.00223801	ETH.MESH.00223828	TVT Retropublic Refresh
4/19/2010	ETH.MESH.00574783	ETH.MESH.00574783	Waltregny D email chain re Your Submission
4/19/2010	ETH.MESH.03627114	ETH.MESH.03627114	Wess A email chain re de leval paper
4/28/2010	ETH.MESH.00750880	ETH.MESH.00750881	TVT Family of Products Co-positioning EWHU Board Pre-Reading
5/12/2010	ETH.MESH.02340902	ETH.MESH.02340973	TVT-O IFU (-present)
5/14/2010	ETH.MESH.01320395	ETH.MESH.01320519	Biocompatibility Assessment of Medi-Line Use of Down Corning 200 Fluid (100 cst) In Gynecare TVT Products
5/28/2010	ETH.MESH.00493332	ETH.MESH.00493343	Consulting Agreement Requisition Form between Brian J. Flynn and Ethicon
6/14/2010	ETH.MESH.03642659	ETH.MESH.03642659	2011 EWHU Business Planning presentation
6/16/2010	ETH.MESH.05347751	ETH.MESH.05347769	Hart email chain re Investigator-Initiated Studies Policy
6/29/2010			Total Petrochemicals Certificate 10D0649
6/30/2010	ETH.MESH.06869163	ETH.MESH.06869166	Landgrebe email chain re matrix - Cohera
7/5/2010	ETH.MESH.03497846	ETH.MESH.03497847	MD&D Complaint Form - Complaint ID CC1007005
7/5/2010	ETH.MESH.13204508	ETH.MESH.13204521	Email Kathie Chen to Darlene Jane Kyle, et al. re Product Complaint CC1007005-Taiwan
7/6/2010	ETH.MESH.02254165	ETH.MESH.02254165	Beath C email chain re 510K clearance
7/12/2010	ETH.MESH.13896042	ETH.MESH.13896043	Poulot email chain re BHR EWHU 3413118, 398077, 3405428
7/13/2010	ETH.MESH.01675805	ETH.MESH.01675806	Samuel S email re Key Steps Flashcare Clarification
7/15/2010	ETH.MESH.02019485	ETH.MESH.02019485	Email Vincenza Zaddem to Alyssa Kilayko re obt muscle thickness values
8/3/2010	ETH.MESH.14967283	ETH.MESH.14967283	Complaint Number: PI1-F8GCTO
8/3/2010	ETH.MESH.14908783	ETH.MESH.14908783	Complaint Number: PI1-EWT0A6

8/8/2010	ETH.MESH.01201955	ETH.MESH.01201956	Page K email re Prof Ed deck (draft 2 still) w/o video
8/11/2010	ETH.MESH.00826028	ETH.MESH.00826045	Hinoul Clinical Expert Report
8/16/2010	ETH.MESH.03432766	ETH.MESH.03432766	Email Brian Flynn to Jonathan Fernandez re permission
8/17/2010	ETH.MESH.13907354	ETH.MESH.13907355	Jaccard email chain re Particles in production w/attachment
8/17/2010	ETH.MESH.13210344	ETH.MESH.13210346	Email Celine Heramza to Carolyn Brennan re Assignment "Product evaluation" has been closed for Issue #:10100122655
8/17/2010	ETH.MESH.03497878	ETH.MESH.03497878	MD&D Resolution Form
8/17/2010	ETH.MESH.01795909	ETH.MESH.01795929	Hinoul Clinical Expert Report
8/24/2010	ETH.MESH.01745568	ETH.MESH.01745572	Email from Carlos E. Lugo-Ponce to Darlene Jane Kyle et al re Product Complaint CC1007005-Taiwan
9/1/2010	ETH.MESH.04101817	ETH.MESH.04101822	Email Shalot Armstrong to Carlos E Lugo-Ponce re Product Complaint CC1007005-Taiwan
9/13/2010	ETH.MESH.03721328	ETH.MESH.03721449	Meier CER Mesh Erosions
9/30/2010	ETH.MESH.08344659	ETH.MESH.08344659	Email Kevin Mahar to Libby Lewis RE: Key docs at AUGS
9/30/2010	ETH.MESH.09218058	ETH.MESH.09218058	Peebles R email re Transcription
11/8/2010	ETH.MESH.10132609	ETH.MESH.10132620	Innovation Council agenda
12/6/2010	ETH.MESH.01226442	ETH.MESH.01226445	Kirkemo A Dear Dr. unsolicited request for information letter
12/6/2010	ETH.MESH.01265511	ETH.MESH.01265511	Kirkemo A email re Your unsolicited request for medical information - MIR
12/9/2010	ETH.MESH.08041930	ETH.MESH.08041931	Irvin email re 12/8 Post Call Notes
12/9/2010	ETH.MESH.06087513	ETH.MESH.06087514	TVTR-566-10-11/12 Physician brochure - Gynecare TVT
12/9/2010	ETH.MESH.05791132	ETH.MESH.05791133	Henderson M email chain re Q4 Spend
1/1/2011	ETHMESH.CHAHAL.00000001	ETHMESH.CHAHAL.00000005	2011 Performance and Development Plan Summary for Chahal



1/20/2011	ETH.MESH.00791766	ETH.MESH.00791813	PowerPoint - Physician Survey Results January 20, 2011
1/22/2011	ETHMESH.CHAHAL.00000052	ETHMESH.CHAHAL.00000063	Lewis L - 2011 Field Visit Letter, Chahal
1/26/2011	ETH.MESH.08003303	ETH.MESH.08003318	Patient Brochure - Treatment Options for Stress Urinary Incontinence -- stop coping. start living.
2/1/2011	ETH.MESH.05276184	ETH.MESH.05276194	Master Consulting Agreement between Dr. Douglas Grier and Ethicon
2/7/2011	ETH.MESH.08003295	ETH.MESH.08003302	TVT-039-11-1/13 Patient brochure - stop coping. start living
2/8/2011	ETH.MESH.06016054	ETH.MESH.06016055	Dang email chain re K103727 - please advise
2/8/2011	ETH.MESH.10630803	ETH.MESH.10630808	Braskem MSDS C4001 Polypropylene
2/14/2011	ETH.MESH.03981288	ETH.MESH.03981290	Roji A email re VOTE team 2010 1:1 calls
2/15/2011	ETH.MESH.05604390	ETH.MESH.05604399	FDA Review of PFR and SUI Mesh Products - Changing Regulatory Environment and Potential Impact on Ethicon Pipeline - presentation
2/16/2011	ETH.MESH.02010834	ETH.MESH.02010855	Biomechanical consideration for Pelvic floor mesh design
2/21/2011	ETHMESH.OHARA.00000347	ETHMESH.OHARA.00000353	Lewis 2010 Performance and Development Plan Summary for O'Hara
2/23/2011	ETH.MESH.02219202	ETH.MESH.02219210	Material Specification for TVT Prolene Polypropylene Mesh Roll Stock, Rev. 5
2/23/2011	ETH.MESH.01216125	ETH.MESH.01216150	Internal Notes - Memo
2/24/2011	ETH.MESH.08005908	ETH.MESH.08005909	Email Jonathan Fernandez to Brian Flynn, et al. re Flynn contracts
2/28/2011	ETH.MESH.00206973	ETH.MESH.00206973	Gauld email re Here is the copy of FDA's letter (please do not forward)
2/28/2011	ETH.MESH.08170224	ETH.MESH.08170232	Kevin Frost email chain re SGS Fellows Symposium
3/7/2011	ETH.MESH.06015196	ETH.MESH.06015196	Benjamin email re FDA ltt re 510k
3/7/2011	ETH.MESH.03898831	ETH.MESH.03898834	Garbarino S email chain re 2011 VOTE Team Conf Call - VOTE Team Questions



3/8/2011	ETH.MESH.00575160	ETH.MESH.00575161	Papas N email chain re AUGS abstract
3/9/2011	ETH.MESH.16434349	ETH.MESH.16434352	Papas N email chain re AUGS Abstract
3/9/2011	ETH.MESH.02592467	ETH.MESH.02592470	Kirkemo A Dear Dr. unsolicited request for information letter
3/11/2011	ETH.MESH.05276086	ETH.MESH.05276097	Master Consulting Agreement between Brian J. Flynn and Ethicon
3/13/2011			TVT Patient Brochure Chart - TVT/SUI Patient Brochures
3/14/2011	ETH.MESH.05163323	ETH.MESH.05163325	Email Alyson Wess to Georgia Long, et al. re
3/15/2011	ETH.MESH.18846146	ETH.MESH.18846147	Kaminski email chain re Prosima Preparation
3/15/2011	ETH.MESH.12627553	ETH.MESH.12627577	Elaine Wise Product Monograph
3/17/2011	ETH.MESH.04062405	ETH.MESH.04062407	Wess A email chain re Incontinence PMT: 3/3 meeting notes
3/29/2011	ETH.MESH.08969368	ETH.MESH.08969368	Frost K email re PF Summit Presentations
3/31/2011	ETH.MESH.07236294	ETH.MESH.07236295	Hinoul email chain re Workshop on Vaginal Tapes
3/31/2011	ETH.MESH.11790162	ETH.MESH.11790162	Phillips, K email re Lack of quality engineering support for Prosima+M
3/31/2011	ETH.MESH.10818814	ETH.MESH.10818814	EWHU: Faculty Training - Sonoma CA Agenda
4/1/2011	ETH.MESH.10818815	ETH.MESH.10818816	Ethicon 2011 Incontinence & Pelvic Floor Summit agenda
4/19/2011	ETH.MESH.00540629	ETH.MESH.00540629	Monthly Complaint Review
4/21/2011	ETH.MESH.10818812	ETH.MESH.10818813	Frost K email re 2011 Incontinence & Pelvic floor REcap
5/13/2011	ETH.MESH.05822684	ETH.MESH.05822693	Email Laura Hutto to Brian Luscombe re Flynn
5/16/2011	ETH.MESH.03643726	ETH.MESH.03643726	US EWHU Executive Performance Review Presentation
5/18/2011	ETH.MESH.02589032	ETH.MESH.02589079	PA Consulting Group Report: Investigating Mesh Erosion in Pelvic Floor Repair
5/18/2011	ETH.MESH.03750903	ETH.MESH.03750950	Berman, Robinson, Wang, Rhodes - Report - Investigating Mesh Erosion in Pelvic Floor Repair

6/22/2011	ETH.MESH.07192929	ETH.MESH.07192929	Investigating Mesh erosion in Pelvic Floor Repair - Report Bernman, Robinson, Wang Rhodes - presentation
6/30/2011	ETH.MESH.07903682	ETH.MESH.07903683	Affeld, T email chain re PS vs +M
7/6/2011	ETH.MESH.05337217	ETH.MESH.05337220	Miller D email chain re Prolift professional education
7/6/2011	ETH.MESH.05337225	ETH.MESH.05337228	Luscombe B email chain re request from Miller re lecture material
7/13/2011	N/A	N/A	FDA Public Health Notification
7/13/2011	ETH.MESH.02253078	ETH.MESH.02253079	Email Bridget Ross (WW President, EWH&U) re FDA Health Notification
7/20/2011			Letter Dr. David Challoner to Dr. Jeffrey E. Shuren re seven recommendations proposed by FDA
7/22/2011	ETH.MESH.17556556	ETH.MESH.17556556	Chahal R email chain re Umaima Jamaluddin procedure questions
7/29/2011	ETH.MESH.00301367	ETH.MESH.00301369	Email Vijay Madikonda re BSI Technical File Audit - July 28-29, 2011
8/26/2011	ETH.MESH.06261965	ETH.MESH.06261967	Karl J email chain re Braskem. . . A Little History
8/30/2011	ETH.MESH.11175841	ETH.MESH.11175842	Samuel S email re Mesh Data
9/30/2011			FDA - Considerations about Surgical Mesh for SUI
10/6/2011	ETH.MESH.11445493	ETH.MESH.11445494	Email Libby Lewis to Mary Byerly re Western Region Needs
12/6/2011	ETH.MESH.09977270	ETH.MESH.09977271	PLT 12 month post-launch close out PPT - slide 17 Executive Summary.
1/30/2012	ETHMESH.OHARA.00000354	ETHMESH.OHARA.00000359	O'Hara 2011 Performance and Development Plan Summary - Libby Lewis
2/1/2012	ETH.MESH.09155883	ETH.MESH.09155895	Grier Consulting Agreement Requisition Form
2/1/2012	ETH.MESH.09155909	ETH.MESH.09155920	Consulting Agreement Requisition Form - Part I Ethicon and Melvyn A. Anhalt

2/6/2012	ETH.MESH.17556591	ETH.MESH.17556593	Chahal R email re Booking Confirmation Jeremy William Aaron - Phoenix, Feb 13
2/16/2012	ETH.MESH.03644217	ETH.MESH.03644217	PowerPoint - EWHU Incontinence 2012 Pipeline Refresh
2/24/2012	ETH.MESH.07730291	ETH.MESH.07730295	Lapinskas, I, email chain originating re Discussion of 3.5 mil Prolene production
3/1/2012	ETH.MESH.07226377	ETH.MESH.07226379	Vellucci, L email chain re Polypropylene Mesh
3/1/2012	ETH.MESH.04015102	ETH.MESH.04015104	Batke B email chain re AGES Pelvic Floor Conference - Gala Dinner Invitation
3/3/2012	ETHMESH.OHARA.00000313	ETHMESH.OHARA.00000314	O'Hara Employee Profile
3/6/2012	ETH.MESH.07455220	ETH.MESH.07455221	Response to MHRA inquiry regarding inertness of polypropylene mesh
3/7/2012	ETH.MESH.02652179	ETH.MESH.02652317	Issues Report Run Between and
3/12/2012	ETH.MESH.07205369	ETH.MESH.07205370	Savidge, et al response to email from Huntington re 'Clave' publication
3/12/2012	ETH.MESH.05998775	ETH.MESH.05998778	Hinoul P email chain re Patient complication in Wichita, KS
3/14/2012	ETH.MESH.07724068	ETH.MESH.07724080	Independent MD&D Sector Audit by QualityHub, Inc. Pore size
3/15/2012	ETH.MESH.04037600	ETH.MESH.04037600	Innovations in Mesh Development by Boris Batke
3/25/2012	ETH.MESH.13681529	ETH.MESH.13681532	The efficacy she needs with less mesh
4/2/2012	ETH.MESH.17556496	ETH.MESH.17556497	Barnes C email chain re Ethicon Gynecare Innovations Event
4/3/2012	ETH.MESH.17556511	ETH.MESH.17556511	Barnes C email chain re ACT REQ: Urgent quick need request
4/3/2012	ETH.MESH.17556598	ETH.MESH.17556598	Chahal R email chain re ACT REQ Urgent quick need
4/4/2012	ETH.MESH.17556512	ETH.MESH.17556512	Langen B email re SMII Welcome Letter
4/5/2012	ETH.MESH.17556486	ETH.MESH.17556487	Luscombe B email re Brand Team for Inc POP
4/12/2012	ETH.MESH.17556513	ETH.MESH.17556513	Langen B letter re Sales Mastery II
4/12/2012	ETH.MESH.17556498	ETH.MESH.17556498	Ethicon Gynecare Innovations flyer

4/27/2012	ETH.MESH.05572526	ETH.MESH.05572528	Hinoul P email chain re slings at surgery center
5/1/2012	ETH.MESH.08066401	ETH.MESH.08066414	Pramudji fax re Contract
5/15/2012	ETH.MESH.08065931	ETH.MESH.08065943	Master Consulting Agreement between Melvyn A. Anhalt and Ethicon
5/18/2012	ETHMESH.CHAHAL.00000051	ETHMESH.CHAHAL.00000051	Chahal Employee Profile
6/14/2012	ETH.MESH.05815791	ETH.MESH.05815802	TVT-172-12-6/14 Patient Brochure - Stop Coping. START LIVING. WHAT YOU SHOULD KNOW ABOUT STRESS URINARY INCONTINENCE
6/16/2012	ETH.MESH.09158424	ETH.MESH.09158430	ARTISYN Advisory Board notes
7/26/2012	ETH.MESH.05125293	ETH.MESH.05125297	Email Piet Hinoul to Axel Arnaud re article "The perils of commercially driven surgical innovation"
8/6/2012	ETH.MESH.13376756	ETH.MESH.13376758	Work Instructions for In-Process & Finished Goods Defect Classifications for Ethicon Products, Appendix 8 - Mesh
8/6/2012	ETH.MESH.13376759	ETH.MESH.13376768	Primary Blister Defect Definitions and Classifications Release Level: 4. Production
8/7/2012	ETH.MESH.09478633	ETH.MESH.09478636	Chen email chain re New Complaint Form 23125
8/7/2012	ETH.MESH.11529265	ETH.MESH.11529266	Doyle email chain re Surgeon request for follow up 10100175641
8/20/2012	ETH.MESH.09478684	ETH.MESH.09478688	Chen M email chain re Urgent - MDR serious injuries Gynecare France
1/6/2013	ETH.MESH.03685918	ETH.MESH.03685925	Amin D Gynecare Protfolio Presentation
1/11/2013	ETH.MESH.13374555	ETH.MESH.13374558	Chung email chain re Gynecare RFP
1/21/2013	ETH.MESH.14348386	ETH.MESH.14348388	Tait email chain re Non conform lids
2/15/2013	ETH.MESH.13274846	ETH.MESH.13274847	Connaughton email chain re New litigation Prolift & TVT
2/15/2013	ETH.MESH.13274855	ETH.MESH.13274856	Connaughton email chain re new litigation Prolift & TVT
3/11/2013			Hellhammer_091113_04 - Designation Run Report

3/20/2013	ETH.MESH.13208194	ETH.MESH.13208196	Connaughton email chain re New litigation TVT
3/20/2013	ETH.MESH.10633520	ETH.MESH.10633528	Revision History of MS-0000108
3/26/2013	ETH.MESH.08073801	ETH.MESH.08073803	Rahman communication - AUGS Issues Statement Opposing the Restriction of Surgical Options for Pelvic Floor Disorders
4/25/2013	ETH.MESH.02342194	ETH.MESH.02342194	IFU Index and Production Bates Range Chart
5/3/2013	ETH.MESH.09744870	ETH.MESH.09744871	TVT 20130503
5/3/2013	ETH.MESH.10287104	ETH.MESH.10287439	Hinoul CER Gynecare TVT Family of Products
5/8/2013	ETH.MESH.09909830	ETH.MESH.09909882	Biocompatibility Risk Assessment Report for Gynecare TVT Product Family
5/23/2013	ETH.MESH.13259844	ETH.MESH.13259845	Connaughton email chain re New litigation
5/24/2013	N/A	N/A	IFU__in_Use__Production_Chart
6/5/2013	ETH.MESH.14852591	ETH.MESH.14852592	McNelis email re new litigation TVT & Prosima
6/5/2013	ETH.MESH.14901756	ETH.MESH.14901757	McNelis email re new litigation TVT & Prosima
6/19/2013	ETH.MESH.09732998	ETH.MESH.09733718	Issue Reports Open Date BEtween 01-Jan-2005 and 02-Jun-2013
6/21/2013	ETH.MESH.12910023	ETH.MESH.12910026	Weisberg email chain re TVT mesh elongation FW: dr. Kenny Maslow
6/21/2013	ETH.MESH.12910030	ETH.MESH.12910032	Weisbert email chain re TVT mesn elongation FW: Dr. Kenny Maslow
6/25/2013	ETH.MESH.12910111	ETH.MESH.12910113	Weisberg email chain re TVT mesh enlongation - Redacted
6/27/2013	ETH.MESH.08315779	ETH.MESH.08315810	Ex T-722 Mitchell - Clinical Expert Report Gynecare Prolift +M
7/19/2013	ETH.MESH.10150515	ETH.MESH.10150849	Clinical Evaluation Report Gynecare TVT Family of Products
8/5/2013	ETH.MESH.12877116	ETH.MESH.12877117	Amin email chain re HPG Pelvic Floor RFP
8/19/2013	ETH.MESH.13292806	ETH.MESH.13292807	Finch email chain re New litigation TVT-S
8/26/2013	N/A	N/A	TVT Patient Brochure Index 8-26-13
8/28/2013	ETH.MESH.12913351	ETH.MESH.12913356	Hinoul email re MIR TVT - ilioninguinal pain w/attachment

9/12/2013			Hellhammer_091213_03 - Designation Run Report
9/17/2013	ETH.MESH.12906504	ETH.MESH.12906506	Librojo email chain re Copy Review Exception
9/21/2013	ETH.MESH.13296239	ETH.MESH.13296240	Gallo email chain re new litigation TVT
9/30/2013	ETH.MESH.10591939	ETH.MESH.10591949	Angelini Browse JJEDS Object Detail form
11/7/2013	ETH.MESH.15034561	ETH.MESH.15034562	McNelis email new litigation TVT
11/7/2013	ETH.MESH.12907174	ETH.MESH.12907174	Jacobs email chain re defect to harms map
11/9/2013	ETH.MESH.14896228	ETH.MESH.14896229	Finch email re new litigation TVT
1/3/2014			AUGS Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence
1/6/2014	ETH.MESH.14852593	ETH.MESH.14852595	Killins email chain re Addtl info - new litigation TVT & Prosima
1/6/2014	ETH.MESH.14901758	ETH.MESH.14901760	Killins email chain re Addtl info new litigation TVT & Prosima
1/9/2014	ETH.MESH.17640736	ETH.MESH.17640767	Corrado email re QRB presentation
1/30/2014	ETH.MESH.14994657	ETH.MESH.14994659	Tran email chain re Addtl Info -
1/31/2014	ETH.MESH.14967286	ETH.MESH.14967287	Jackson email chain Addtl Info -
2/4/2014	N/A	N/A	United States Patent De Leval US8641597
2/4/2014	ETH.MESH.14896230	ETH.MESH.14896232	Piper email chain re Addtl info
2/5/2014			Exhibit T-3604 LCM sales inside the US
2/6/2014	ETH.MESH.16357097	ETH.MESH.16357097	Sedlatschek email chain re Secant Medical Inquiry on Gynecare Mesh Products
2/7/2014	ETH.MESH.17777763	ETH.MESH.17777768	Sedlatschek email re Secant Medical Inquiry on Gynecare Mesh Products
2/7/2014	ETH.MESH.14896233	ETH.MESH.14896235	Tran email chain re addtl info 1/30/14
3/26/2014	HMESH_ETH_06033196	HMESH_ETH_06033202	Rodriguez email chain re Nilsson 2013
3/27/2014	ETH.MESH.17619399	ETH.MESH.17619405	Rodriguez email chain re Secant Medical Inquiry on Gynecare Mesh Products
4/14/2014	ETH.MESH.17642669	ETH.MESH.17642686	PQI Revision 10
5/2/2014	ETHMESH.OHARA.00000360	ETHMESH.OHARA.00000362	O'Hara Career Development Profile

5/19/2014	ETH.MESH.17777759	ETH.MESH.17777762	Rodriguez email chain re UPDATE to Escalation Notice - Section 39 Request - TVT, Gynemesh PS & Artisyn Y-Shared Mesh
6/9/2014			Total Units Sold Chart - Product data
6/20/2014			Letter Dr. Aileen Keel to Colleague re Transvaginal mesh implants
6/28/2014			Management of Mesh Complications AUGS and IUGA 2014 CButrick
7/17/2014	ETHMESH.CHAHAL.00000049	ETHMESH.CHAHAL.00000050	Chahal Career Development Profile
12/2/2014			About Banque Carnegie Luxembourg - HL - Banque Carnegie Luxembourg
2/2/2015			tvf lightweight Google search
2/17/2015	ETH.MESH.03625982	ETH.MESH.03625982	List of Preceptor Names and Events Attended
2002	ETH.MESH.00340836	ETH.MESH.00340838	CER Update for TVT
2002			ASTM D 1388-96 - Standard Test Method for Stiffness of Fabrics
2003	HMESH_ETH.07269753	HMESH_ETH.07269765	Contact Points - Nummular allergic contact dermatitis after scabies treatment, R. Kaminska, et al
2003			T 437 om -03 Dirt in Paper and Paperboard
2006			AMS Solutions for Life Preserving Mesh Integrity, Simplifying Tensioning
2006	ETH.MESH.00746209	ETH.MESH.00746209	Product Pointer
2007	ETH.MESH.08003247	ETH.MESH.08003262	TVT 20070531 Patient Brochure - The Choice to End Stress Urinary Incontinence Find out how to stop urine leakage like Bonnie did
2007	ETH.MESH.06861946	ETH.MESH.06861946	Basell Purell MSDS
2007	ETH.MESH.00163582	ETH.MESH.00163597	Brochure "Find out how to stop urine leakage like Bonnie did"
2008	ETH.MESH.07474296	ETH.MESH.07474407	ANSI/AAMI/ISO 10993-7:2008



2008	ETH.MESH.00658453	ETH.MESH.00658458	Brochure The Gynecare TVT Family of Products 3 SUI Solutions. Delivering Data, Safety & Choice.
2009	ETH.MESH.00002162	ETH.MESH.00002177	Stop coping. Start living
2010	ETH.MESH.00499024	ETH.MESH.00499024	2010 preceptor payments spreadsheet
2010	ETH.MESH.00346194	ETH.MESH.00346201	The efficacy she needs with less mesh - annotated - round 3
2010	ETH.MESH.06260647	ETH.MESH.06260671	R&D CO-OP Welcome Guide Spring 2010
2010	ETH.MESH.02236784	ETH.MESH.02236785	Physician patient follow-up form letter
2011	ETH.MESH.00790545	ETH.MESH.00790546	Competitive Dissection Flashcard
2011	ETH.MESH.14273633	ETH.MESH.14273668	Ethicon Neuchâtel A changing Product Protfolio
2011	ETH.MESH.08078799	ETH.MESH.08078799	TVT-US
2011	ETHMESH.CHAHAL.00000044	ETHMESH.CHAHAL.00000048	ChahalHospital Sales Spreadsheet
2011	ETH.MESH.04005863	ETH.MESH.04006038	Ozog, Yves Doctorial Thesis: Theoretical and Experimental Evaluation of Implant Materials Used in Pelvic Organ Prolapse Repair
2011	ETH.MESH.17556578	ETH.MESH.17556579	2011 Price List
2012	ETH.MESH.09744848	ETH.MESH.09744855	TVT-312-12 Patient Brochure - stop coping. start living. GYNECARE TVT Family of Products
2012	ETH.MESH.07808484	ETH.MESH.07808486	Frequently Asked Questions Clinical Data Review 3-Year Data Flashcard
2013	ETH.MESH.16308087	ETH.MESH.16308090	Patient Brochure
2013	ETH.MESH.09744840	ETH.MESH.09744845	TVT-131-13 Patient Brochure - stop coping start living. What You Should Not About Stress Urinary Incontinence
2013			AUA 2013 Annual Meeting Highlights Voiding Dysfunction/Female Urology
2014	T-1499	T-1499	Total Units Sold Chart
2014			Webpage "A Solution: Gynecare TVT Tension-free Support for Incontinence"
1/2002	ETH.MESH.08793554	ETH.MESH.08793554	DTC Advertising Patient Potential January 2002 Presentation



1/2010	ETH.MESH.03643186	ETH.MESH.03643186	Ethicon Women's Health and Urology Brand Equity Study Final Report
2/2002	ETH.MESH.00339437	ETH.MESH.00339442	5 Years of Proven Performance TVT Sales Aid (TVT041)
3/2011	ETH.MESH.05479717	ETH.MESH.05479717	ETHICON Polypropylene Mesh Technology- Batke presentation
4/2008	ETH.MESH.00006636	ETH.MESH.00006636	Klosterhalfen Interim report mesh explants pelvic floor repair
6/2000	ETH.MESH.00400957	ETH.MESH.00400978	TVT Surgeons Resource Monograph
6/2003			Clark Urological Center Newsletter
7/2002	ETHMESH.OHARA.00000304	ETHMESH.OHARA.00000312	O'Hara Application for Employment
7/2009	ETH.MESH.05764101	ETH.MESH.05764101	BUC July 2009 I&pf platforms presentation
7/2013			ICS Fact Sheets A Background to Urinary and Faecal Incontinence prepared by the Publications & Communications Committee, July 2013
8/2009	ETH.MESH.00533025	ETH.MESH.00533026	HS Study Monthly Update
8/2010	ETH.MESH.03422160	ETH.MESH.03422162	Clinical Data Review Presented at ICS/IUGA Aug 2010
9/2004	ETH.MESH.03571983	ETH.MESH.03572098	Physician Segmentation Study for Gynecare TVT Final Presentation - Copernicus
9/2007	HMESH_ETH_00660369	HMESH_ETH_0066078	Pleiger - Polyamid.nylon MSDS
9/2010	ETH.MESH.09932902	ETH.MESH.09932912	Neuchatel - September 2010 Roles and Responsibilities
9/2010	ETH.MESH.09932908	ETH.MESH.09932918	Neuchatel - September 2010 Roles and Responsibilities
10/2000	ETH.MESH.04044797	ETH.MESH.04044800	TVT Update Success & Complications - Bernard Jacquetin
10/2008	ETH.MESH.17556582	ETH.MESH.17556582	IFPM position on FDA notification
10/2011			AUA HP Brief - Billing for Sling Revisions and Urethrolysis

10/2012	ETH.MESH.07808480	ETH.MESH.07808481	The efficacy she need with less mesh. Clinical Data Review - 3 Year Data
	ETH.MESH.08426862	ETH.MESH.08426867	Toglia Presentation - The Mesh Story working copy
	HMESH_ETH_06509816	HMESH_ETH_06509816	Text File
			Study Slides - various testimony
			Jordi SEM and OM Images
			Chart of Responsive Documents
	ETH.MESH.11175843	ETH.MESH.11175843	The Science of "What's Lift Behind" . . . presentation
	ETH.MESH.01592467	ETH.MESH.01592490	Test Method Validation Protocol: Visual Acceptance criteria for seal of Blister PVA-112940-TMV-PR
	ETH.MESH.09214439	ETH.MESH.09214439	Toglia, The Mesh Story presentation
	ETH.MESH.04941016	ETH.MESH.04941049	Holste presentation: Lightweight Mesh Developments
	ETH.MESH.14901753	ETH.MESH.14901753	Complaint P11E8VOWN
	ETH.MESH.15406916	ETH.MESH.15406919	Guidoin Lab Notebook Page/Image
	ETH.MESH.13797826	ETH.MESH.13797830	Check Liste D'Inspection Qualite
	ETH.MESH.13376661	ETH.MESH.13376868	Draft Template: DRM for Device Functionality (Performance & Safety)
	ETH.MESH.00301977	ETH.MESH.00301977	TVT Laser Cut Mesh Project Revision History for DFMEA0000242
	ETH.MESH.09671620	ETH.MESH.09671620	Material specification spreadsheet
	ETH.MESH.00632655	ETH.MESH.00632655	U.S. Launch Overview
			CV of Piet Hinoul
	ETH.MESH.15958470	ETH.MESH.15958477	Guidoin Lab Notebook Page/Image
	ETH.MESH.00355435	ETH.MESH.00355435	Differentiation Statement
	ETH.MESH.11175844	ETH.MESH.11175844	TVT Complication comparison matrix
	ETH.MESH.00074499	ETH.MESH.00074499	Presentation: Gynecare Prolift+M Pelvic Floor Repair System Training

	ETH.MESH.02106741	ETH.MESH.02106743	Surgeon Evaluation Questions for Laser Cut Mesh
	ETH.MESH.00271641	ETH.MESH.00271641	Franco presentation - The Science of "What's Left Behind" . . . Evidence & Follow-Up of Mesh Use for SUI
	ETH.MESH.15406979	ETH.MESH.15406981	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406920	ETH.MESH.15406921	Guidoin Lab Notebook Page/Image
	ETH.MESH.08334245	ETH.MESH.08334245	LCM Project: Photographs Comparing Laser Cut Mesh vs Mechanical Cut Mesh
	ETH.MESH.15406956	ETH.MESH.15406957	Guidoin Lab Notebook Page/Image
	ETH.MESH.02108293	ETH.MESH.02108295	Division Meeting Notes: Continence Health
	ETH.MESH.00223800	ETH.MESH.00223800	Powerpoint TVT Retropublic Refresh
	ETH.MESH.14471186	ETH.MESH.14471186	Spreadsheet
	ETH.MESH.08968369	ETH.MESH.08968378	Ailawadi - Does Material Matter - final
	ETH.MESH.01310061	ETH.MESH.01310065	TVT Laser Cut RMR Rev 2
	ETH.MESH.02236580	ETH.MESH.02236595	Patient Brochure - Stop coping. Start Living. Gynecare TVT Family of Products
	ETH.MESH.00581483	ETH.MESH.00581486	Gynecare International Convention Recommendations
	ETH.MESH.03738466	ETH.MESH.03738467	Emails Martin Weisberg and Dr Peggy Norton re TVT
	ETH.MESH.07506983	ETH.MESH.07506985	Biocompatibility Risk Assessment: PROSIMA Pelvic Floor Repair System (Mint)
	ETH.MESH.06866921	ETH.MESH.06866921	ETH.MESH.06866921 attachment
	ETH.MESH.15406942	ETH.MESH.15406943	Guidoin Lab Notebook Page/Image
			Grier with notes T-752
	ETH.MESH.15406958	ETH.MESH.15406960	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406971	ETH.MESH.15406971	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406977	ETH.MESH.15406977	Guidoin Lab Notebook Page/Image
	ETH.MESH.01066916	ETH.MESH.01066932	TVT and TVT-O RMR Rev 1
	ETH.MESH.15406976	ETH.MESH.15406976	Guidoin Lab Notebook Page/Image
	ETH.MESH.13374559	ETH.MESH.13374559	RFI Instructions

	ETH.MESH.05644163	ETH.MESH.05644171	Pelvic Floor Repair -- Surgeon's Feed-back on Mesh Concept
	T-3137	T-3137	Material Safety Data Sheet, Chevron Philips 2004
	ETH.MESH.03730703	ETH.MESH.03730722	Check Liste D'Inspection Qualite - Final TVT-TVT-AA
	ETH.MESH.04321413	ETH.MESH.04321417	Check Liste D'Inspection Qualite
	ETH.MESH.15406906	ETH.MESH.15406909	Guidoin Lab Notebook Page/Image
	ETH.MESH.04077109	ETH.MESH.04077145	Grier Presentation - The Science of "What's Left Behind" . . . Evidence & Follow-Up of Mesh Use for SUI
			Copy of IFU__in_Use__Production_Chart
	ETH.MESH.01310482	ETH.MESH.01310482	Spreadsheet DFMEA's TVT Classic
			Gynecare_Professional_Education_Digital_Library
	ETHMESH.CHAHAL.00000028	ETHMESH.CHAHAL.00000048	Chahal sales spreadsheets
			Degradation Slides
	ETH.MESH.00353476	ETH.MESH.00353476	Annotated Slide
	ETH.MESH.05442973	ETH.MESH.05442975	Applied Science & Technology Performance Evaluation Abstract Biaxial testing of two commonly used Ethicon meshes
	ETH.MESH.15406846	ETH.MESH.15406856	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406929	ETH.MESH.15406930	Guidoin Lab Notebook Page/Image
	ETH.MESH.00223634	ETH.MESH.00223655	DHF0000747 TVT Retropublic Refresh
	ETH.MESH.00589494	ETH.MESH.00589494	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.04081871	ETH.MESH.04081872	Chen, Medical Assessment - . . . 68 issues from Germany
	ETH.MESH.01226446	ETH.MESH.01226449	Dr. Letter
	ETH.MESH.15406944	ETH.MESH.15406945	Guidoin Lab Notebook Page/Image
			Design FMEA: TVT Laser Cut Mesh Project spreadsheet
	ETH.MESH.03932912	ETH.MESH.03932914	The history of TVT

	ETH-50330	ETH-50330	Slide: Selecting the Right Mesh
	ETH.MESH.15406954	ETH.MESH.15406955	Guidoin Lab Notebook Page/Image
	ETH.MESH.11175864	ETH.MESH.11175864	Gynecare TVT Exact Gynecare TVT Tension-free Support for Incontinence Clinical Data Presentation
	ETH.MESH.03751168	ETH.MESH.03751168	Table comparing meshes
	ETH.MESH.15406975	ETH.MESH.15406975	Guidoin Lab Notebook Page/Image
	HMESH_ETH_02781707	HMESH_ETH_02781708	Stockholm Trip Report
	ETH.MESH.00826046	ETH.MESH.00826047	Product Complaints Graph
	ETH.MESH.03924530	ETH.MESH.03924539	2.0 Products in Development
	ETH.MESH.15406924	ETH.MESH.15406926	Guidoin Lab Notebook Page/Image
			Flexibility/Compliance
	ETH.MESH.04321418	ETH.MESH.04321435	Check Liste D'Inspection Qualite
	ETH.MESH.02249435	ETH.MESH.02249435	New Product Introduction Presentation
	ETH.MESH.02342102	ETH.MESH.02342102	Prolene
	N/A	N/A	Chart of Responsive Documents
	ETH.MESH.00858252	ETH.MESH.00858253	London Brown Memo to Smith re Mechanical Cut vs Laser Cut Mesh Rationale
	ETH.MESH.15406987	ETH.MESH.15406988	Guidoin Lab Notebook Page/Image
	ETH.MESH.01752532	ETH.MESH.01752535	Trzewik - Mesh design argumentation issues
	ETH.MESH.15406893	ETH.MESH.15406894	Guidoin Lab Notebook Page/Image
	ETH.MESH.02237665	ETH.MESH.02237696	Spanish Gynecare TVT patient brochure
	ETH.MESH.02182839	ETH.MESH.02182844	Completion Report, Design Verificaiton for Soft PROLENE Mesh/Mesh Curling
	ETH.MESH.15406998	ETH.MESH.15406999	Guidoin Lab Notebook Page/Image
	ETH.MESH.00748275	ETH.MESH.00748275	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.00223640	ETH.MESH.00223640	Spreadsheet TVT Retropublic Refresh
	ETH.MESH.01310476	ETH.MESH.01310481	TVT RMR Rev 3
	PM.00003.m4v	PM.00003.m4v	Training Videos
	ETH.MESH.06171801	ETH.MESH.06171801	Spreadsheet
	ETH.MESH.15406897	ETH.MESH.15406899	Guidoin Lab Notebook Page/Image

	ETH.MESH.09905193	ETH.MESH.09905193	Survey Results
	ETH.MESH.08505071	ETH.MESH.08505071	Cecchini TVT package insert comments
	ETH.MESH.05119622	ETH.MESH.05119631	Commonly Asked Questions and Objections script
	ETH.MESH.15406961	ETH.MESH.15406962	Guidoin Lab Notebook Page/Image
	ETH.MESH.03905968	ETH.MESH.03905975	Gynecare Pro-lift Ad "Get the Facts, Be Informed, Make YOUR Best Decision"
	ETH.MESH.17556583	ETH.MESH.17556583	Physician Consultation Visit Regarding Decision for Surgery Form
	ETH.MESH.15958510	ETH.MESH.15958511	Guidoin Lab Notebook Page/Image
	ETH.MESH.09004555	ETH.MESH.09004555	Elongation test data - delayed launch
	ETH.MESH.13860322	ETH.MESH.13860342	Check Liste D'Inspection Qualite
			AUGS-SUFU Position Statement drafts
	ETH.MESH.00161444	ETH.MESH.00161445	TVT Detail Sheet (TVTOO1R
	ETH.MESH.15406990	ETH.MESH.15406991	Guidoin Lab Notebook Page/Image
	ETH.MESH.09004554	ETH.MESH.09004554	Elongation test data
	ETH.MESH.08792102	ETH.MESH.08792106	Risk Management Report TVT Laser Cut Mesh (LCM) Revision History for (RMR-000017) Revision 2
	ETH.MESH.01419741	ETH.MESH.01419741	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.04321436	ETH.MESH.04321453	Check Liste D'Inspection Qualite
	ETH.MESH.15406871	ETH.MESH.15406873	Guidoin Lab Notebook Page/Image
	ETH.MESH.02106803	ETH.MESH.02106803	Physician Post-Operative Questionnaire
	ETH.MESH.01250962	ETH.MESH.01250962	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.15406939	ETH.MESH.15406941	Guidoin Lab Notebook Page/Image
	ETH.MESH.00143842	ETH.MESH.00143842	Presentation draft - Tension-Free Support for Female SUI (258 Patients) - Modarelli, et al
	ETH.MESH.15958486	ETH.MESH.15958491	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406884	ETH.MESH.15406885	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406937	ETH.MESH.15406938	Guidoin Lab Notebook Page/Image
	ETH.MESH.05120364	ETH.MESH.05120365	Mesh vs Non-Mesn Pending PR/Regulatory Issues
			510(k) Submission and Communications for TVT Exact

	ETH.MESH.15406963	ETH.MESH.15406964	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406903	ETH.MESH.15406905	Guidoin Lab Notebook Page/Image
	ETH.MESH.08664680	ETH.MESH.08664686	Franchise Procedure for Controlling Substances of Concern Revision History PR-0000558
	ETH.MESH.15406860	ETH.MESH.15406861	Guidoin Lab Notebook Page/Image
	ETH-53294	ETH-53294	Check Liste D'Inspection Qualite
	ETH.MESH.05237034	ETH.MESH.05237037	Trzewik memo re Mesh design argumentation issues
	ETH.MESH.04082973	ETH.MESH.04082974	Study Notes, Meng Chen, PhD, Possible Complications for Surgeries to Correct Pelvic Organ Prolapse
	ETH.MESH.09748848	ETH.MESH.09748853	Consultancy Agreement
	ETH.MESH.15406888	ETH.MESH.15406889	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406877	ETH.MESH.15406879	Guidoin Lab Notebook Page/Image
	ETH.MESH.15958492	ETH.MESH.15958494	Guidoin Lab Notebook Page/Image
	ETH.MESH.15958495	ETH.MESH.15958502	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406948	ETH.MESH.15406949	Guidoin Lab Notebook Page/Image
	ETH.MESH.09293114	ETH.MESH.09293114	Notes re customers frustration with Ethicon rep
	ETH.MESH.08581280	ETH.MESH.08581282	Equivalence Supported by Pre-clinical Performance Studies
	ETH.MESH.09748842	ETH.MESH.09748846	Consultancy Agreement
	ETH.MESH.15958481	ETH.MESH.15958485	Guidoin Lab Notebook Page/Image
	ETH.MESH.00340835	ETH.MESH.00340835	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.15406864	ETH.MESH.15406866	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406869	ETH.MESH.15406870	Guidoin Lab Notebook Page/Image
	ETH.MESH.15958478	ETH.MESH.15958480	Guidoin Lab Notebook Page/Image
	ETH.MESH.00010743	ETH.MESH.00010743	Letter of Proffer: Madigan Army Medical Center
	ETH.MESH.15958512	ETH.MESH.15958517	Guidoin Lab Notebook Page/Image
	ETH.MESH.00301741	ETH.MESH.00301742	Lamont email chain re !!!!Great News for TVT Laser Cut Mesh!!!!
	ETH.MESH.05240144	ETH.MESH.05240144	Article on pp change in sheep model
	ETH.MESH.15406950	ETH.MESH.15406951	Guidoin Lab Notebook Page/Image



	ETH.MESH.15406989	ETH.MESH.15406989	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406874	ETH.MESH.15406876	Guidoin Lab Notebook Page/Image
	ETH.MESH.03906527	ETH.MESH.03906527	Graft or No Graft - Arnaud presentation
			TVT Retropubic Mechanical Cut, US Sales
	ETH.MESH.15406992	ETH.MESH.15406993	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406969	ETH.MESH.15406970	Guidoin Lab Notebook Page/Image
	ETH.MESH.01247379	ETH.MESH.01247379	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.04321405	ETH.MESH.04321408	Check Liste D'Inspection Qualite
	ETH.MESH.08696085	ETH.MESH.08696134	Medscand Agreement Files
	ETH.MESH.08776231	ETH.MESH.08776238	Instruction Standard TVT EXACT product Plan and Rationald Appendix I, Revision A
	ETH.MESH.01218099	ETH.MESH.01218103	TVT Laser Cut Mesh Rev 1
	ETH.MESH.01218019	ETH.MESH.01218019	Revision History for dFMEA0000242
	N/A	N/A	Trial Testimony of Piet Hinoul in Linda Gross Trial
	ETH.MESH.00321804	ETH.MESH.00321805	Definition for Major Invasive Surgeries and The Ethicon Franchise Products Requiring Major Invasive Procedures for Implantation
	ETH.MESH.03671138	ETH.MESH.03671147	MS455-012; Revision 18 Material Specification for Pelletized Unpigmented
	ETH.MESH.15406952	ETH.MESH.15406953	Guidoin Lab Notebook Page/Image
	ETH.MESH.00746210	ETH.MESH.00746212	Surgeon Evaluation Questions for Laser Cut Mesh
	N/A	N/A	Trial Testimony of Melvyn Anhalt, MD in the Linda Batiste Trial
	ETH.MESH.00862284	ETH.MESH.00862289	MS729-XXX;Appendix 1
	ETH.MESH.06195201	ETH.MESH.06195205	Divilio memo
	ETH.MESH.04321454	ETH.MESH.04321471	Check Liste D-Inspection Qualite
	ETH.MESH.15406900	ETH.MESH.15406902	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406985	ETH.MESH.15406986	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406867	ETH.MESH.15406868	Guidoin Lab Notebook Page/Image
	ETH.MESH.14221357	ETH.MESH.14221357	Spreadsheet
	ETH.MESH.15406862	ETH.MESH.15406863	Guidoin Lab Notebook Page/Image



	ETH.MESH.15406972	ETH.MESH.15406972	Guidoin Lab Notebook Page/Image
	ETH.MESH.11917445	ETH.MESH.11917450	TVT Family of Products Sales Rep Promotion TVT Fast Break
	ETH.MESH.13869615	ETH.MESH.13869634	Check Liste D'Inspection Qualite Final TVT/TVT-AA
	ETH.MESH.05479535	ETH.MESH.05479535	Mesh porosity chart
	ETH.MESH.00159634	ETH.MESH.00159719	Toth Memo w/ Gynecare TVT Professional Education Slides
	ETH.MESH.01250926	ETH.MESH.01250926	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.15406967	ETH.MESH.15406968	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406927	ETH.MESH.15406928	Guidoin Lab Notebook Page/Image
			TVT product sales
	ETH.MESH.00528636	ETH.MESH.00528641	Product Quality Plan for Gynecare Gynemesh XL
	ETH.MESH.15406890	ETH.MESH.15406892	Guidoin Lab Notebook Page/Image
	ETH.MESH.15406895	ETH.MESH.15406896	Guidoin Lab Notebook Page/Image
	ETH.MESH.02265803	ETH.MESH.02265809	Spreadsheet DFMEA's TVT Classic
	ETH.MESH.00858080	ETH.MESH.00858081	Smith D Memo re Gynecare Board risk discussion before launch
			Vypro Mesh - Prolene Mesh
	ETH.MESH.15406965	ETH.MESH.15406966	Guidoin Lab Notebook Page/Image
	ETH.MESH.10181793	ETH.MESH.10181797	Ulmsten - Anesthesiological routines for the TVT Procedure
			CV of Katrin EK Elbert, PhD
	ETH.MESH.15406935	ETH.MESH.15406936	Guidoin Lab Notebook Page/Image
	ETH.MESH.15958503	ETH.MESH.15958507	Guidoin Lab Notebook Page/Image
	ETH.MESH.00998286	ETH.MESH.00998291	Weisberg M Final Draft CER
	ETH.MESH.12907175	ETH.MESH.12907175	Spreadsheet Revision History - Defect to Harms Map
	ETH.MESH.04321409	ETH.MESH.04321412	Check Liste D-Inspection Qualite
	ETH.MESH.05210364	ETH.MESH.05210365	Mesh vs Non-Mesh Pending PR/Regulatory Issues

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9/22/2004	ETH.MESH.00126954	ETH.MESH.00126955	Email re: Preceptor "Voicemails"?
2004	ETH.MESH.00155598	ETH.MESH.00155600	2004 press release
From Metadata:01/01/05	ETH.MESH.00155619	ETH.MESH.0155627	Patient Brochure
	ETH.MESH.00158082	ETH.MESH.00158082	Tips for Scheduling you appointment
2000	ETH.MESH.00160615	ETH.MESH.00160623	TVT Brochure
1/16/2009	ETH.MESH.00161969	ETH.MESH.00161984	TVT Brochure
From Metadata: 01/06/06	ETH.MESH.00162841	ETH.MESH.00162856	TVT Brochure
2007	ETH.MESH.00163644	ETH.MESH.00163659	Patient Brochure
10/21/2008	ETH.MESH.00164023	ETH.MESH.00164027	FDA Notification About Use of Surgical Mesh
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2004	ETH.MESH.08692670	ETH.MESH.08692672	2004 Cancellation Agreement
9/13/2010	ETH.MESH.00869977	ETH.MESH.00870098	Clinical Evaluation Report Mesh Erosions
11/16/2005	ETH.MESH.00875647	ETH.MESH.00875649	11/16/05 Email from Carol Brennan
2001	ETH.MESH.01137272	ETH.MESH.01137293	2001 Marketing Plan
	ETH.MESH.01186068	ETH.MESH.01186072	Make Data and Safety Your Choice
1/1/2009	ETH.MESH.01202102	ETH.MESH.01202104	Email re: My revised writeup of the DeLeval and Waltregny visit
4/19/2001	ETH.MESH.01203207	ETH.MESH.01203260	Labeling FDA Guidance
11/14/2008	ETH.MESH.01203957	ETH.MESH.01203957	Future of surgical meshes presentation
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10/18/2006	ETH.MESH.01822361	ETH.MESH.01822363	10/18/06 Email from Dan Smith
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	ETH.MESH.02340306	ETH.MESH.02340369	TVT IFU
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	ETH.MESH.02621559	ETH.MESH.02622455	01/01/2001-12/31/01 TVT issue reports
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10/15/1992	ETH.MESH.05453719	ETH.MESH.05453727	Prolene Study
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1999	ETH.MESH.08692673	ETH.MESH.08692696	Consulting Agreement 1999
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	ETH.MESH.PM 000019	ETH.MESH.PM 000019	Video
	ETH.MESH.PM 000027	ETH.MESH.PM 000027	Video
	ETH.MESH.PM 000032	ETH.MESH.PM 000032	Video
	ETH.MESH.PM 000037	ETH.MESH.PM 000037	Video
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<b>Deponent</b>	<b>Date</b>
Zenobia Wajli	All dates
Judy Gauld	All dates
Scott Ciarrocca	All dates
Matthew Henderson	All dates
Paul Parisi	All dates
Bryan Lisa	All dates
Sean O'Bryan	All dates
Angelini, Laura, Transcripts and Exhibits	All dates
Arnaud, Axel, MD Transcripts and Exhibits	All dates
Barbolt, Thomas A., Ph.D Transcripts and Exhibits	10/10/2012; 08/04/2013; 08/15/2013; 01/07/2014; 01/08/2014
Batke, Boris Transcripts and Exhibits	8/1-2/2013
Beath, Catherine Transcripts and Exhibits	07/11-12/2013
Burkley, Dan Transcripts and Exhibits	5/22/2013; 5/23/2013
Chen, Meng, MD Transcripts and Exhibits	10/29-30/2013
London-Brown, Allison Transcripts and Exhibits	All dates
Hart, James D., MD Transcripts and Exhibits	09/17/2013; 12/20/2013
Hellhammer, Brigitte, MD Transcripts and Exhibits	09/11-12/2013
Hinoul, Piet Transcripts and Exhibits	04/05/2012; 06/26- 27/2013; 01/13-15/2014
Holste, Joerg Transcripts and Exhibits	07/29-30-2013
Horton, Ron Transcripts and Exhibits	7/1/2015
Isenberg, Richard, MD Transcripts and Exhibits	11/5/13 and 11/6/13

Divilio, Thomas Transcripts and Exhibits	All dates
Kirkemo, Aaron, Transcripts and Exhibits	All dates
Kammerer, Gene, Transcript and Exhibits	All dates
Lin, Susan, Transcripts and Exhibits	3/12-13/2013; 05/3,6/2013; 08/01/2013
Lamont, Daniel J. Transcript	4/3-4/2013; 9/11/2013
Owens, Charlotte Transcript and Exhibits	9/12/2012; 6/20/2013
Robinson, David Transcripts and Exhibits	07/24- 25/2013; 09/11/2013
Selman, Renee Transcript and Exhibits	6/21/2013
Smith, Dan, Transcripts and Exhibits	05/15- 16/2013; 06/04- 05/2013; 08/20-21/2013
Vailhe, Christophe, Ph.D., Transcripts and Exhibits	06/20-21/2013
Weisberg, Martin, MD Transcripts and Exhibits	05/30- 31/2013; 08/09/2013
McCoy, Sheri Transcripts and Exhibits	All dates
Yale, Mark, Transcript and Exhibits	8/7/2013
Trial Testimony of Piet Hinoul - Batiste v. Ethicon	3/26/14; 3/27/14; 3/28/14
Jones, Scot Transcript and Exhibits	6/9/2014
Testimony and Exhibits from Batiste v. Ethicon Trial	

Deposition of Bruce Rosenzweig, MD	9/22/2015
Deposition of Jerry Blaivas, MD	9/17/2015



**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO PLAINTIFFS:</b>  <b>Wave 1 Cases</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**RULE 26 EXPERT REPORT OF DANIEL ELLIOTT, M.D.**

**I. BACKGROUNDS AND QUALIFICATIONS**

I am an Associate Professor of Urology, section of Female Urology and Reconstructive Surgery, at Mayo Clinic Graduate School of Medicine in Rochester, Minnesota. My current curriculum vita, attached hereto as Exhibit "A", more fully and accurately reflects my training, background, academic activity and publications. However, briefly, I received an M.D. in 1993 from Loma Linda University School of Medicine in Loma Linda, California. Following graduation from medical school, I completed one year of General Surgery and five years of Surgical Urology residency at the Mayo Graduate School of Medicine at the Mayo Clinic in 1999. I then completed a one-year advanced surgical fellowship at Baylor College of Medicine in Houston, Texas, in Neurourology, Urodynamics and Voiding Dysfunction. I then re-joined the faculty at the Mayo Clinic, where I have spent the last fifteen years specializing in treating pelvic organ prolapse and urinary incontinence in women and urinary incontinence in men. I have published nearly 60 peer-reviewed articles and given over 100 lectures nationally and internationally pertaining to urinary incontinence and pelvic organ prolapse. I have specifically authored two published scientific manuscripts dealing with polypropylene meshes in the animal model. A Mayo Clinic colleague and I were the first to perform robotic sacrocolpopexy surgery for the treatment of high-grade prolapse and to publish extensively on the subject and the first to perform and publish on the outpatient, non-mesh transobturator sling.

During my training, I was introduced to the use of synthetic midurethral slings for incontinence repair. I have used the Mentor OB/Tape products as well as mesh slings made by AMS and Coloplast. As of over a year ago, I decided to no longer use meshes in my practice through the transvaginal route unless there is absolutely no other alternative. The reason that I made this decision is that my practice has become increasingly dedicated to treating a host of life-altering complications associated with the use of both SUI and POP meshes, including

meshes made by Ethicon. Neither I, nor my colleagues at Mayo, have ever used transvaginal POP kits as we felt that the risk to patients was too great. Having treated hundreds of patients with mesh-related complications (both SUI and POP), I feel that we made the right decision not to include them as part of our treatment regimen. I only use mesh for POP repair through robotic sacrocolpopexy, as it is not a transvaginal surgery, uses much less mesh, and is associated with significantly less complications than transvaginal mesh prolapse repair.

I am a frequent invited national and international lecturer at medical and surgical conferences addressing stress urinary incontinence and pelvic organ prolapse, their evaluation, treatment, surgical options and management of complications. I have taken and passed the subspecialty credentialing process recently established by the combined boards of the American Board of Urology and American Board of Obstetrics and Gynecology in Female Pelvic Medicine and Reconstructive Surgery.

## **II. BASIS OF OPINIONS**

I have been asked to provide opinions regarding the subject of pelvic organ prolapse, its evaluation, treatments, surgical options and management of complications as well as to address the actions of Ethicon, Inc., Ethicon Women's Health and Urology, a Division of Ethicon, Inc., Gynecare and Johnson & Johnson (collectively referred to as Ethicon), regarding its transvaginal mesh pelvic floor repair products for prolapse. The focus of my investigation for this report is on the GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems (collectively referred to as "Prolift" or the "Prolift System"). My opinions are based on my personal knowledge, experience, and my investigation in this case. All of my opinions, and the basis of these opinions, are true and correct to the best of my knowledge and belief, including those related to scientific and medical issues, which I believe are true and correct to a reasonable degree of scientific and medical probability. I do, however, reserve the right to supplement this report and my opinions in light of any additional material or information provided to me, including any reports submitted and/or any other discovery that is taken in this case. Furthermore, if called to testify, I would plan to use various demonstrative exhibits, animations, video recordings, and/or anatomic models to show the relevant anatomy and surgical procedures and to describe my opinions as set forth in this report. The materials I have reviewed and relied upon to form my opinions for this report are attached as Exhibit "B".

## **III. SUMMARY OF OPINIONS**

### **A. Lack of Clinical Benefit**

1. Overall, patients implanted with non-absorbable, transvaginal synthetic mesh for pelvic organ prolapse, including the Prolift System, do not have demonstrable improvement in symptomatic results over traditional, non-mesh repair.
2. Overall, patients implanted with non-absorbable, transvaginal synthetic mesh for pelvic organ prolapse, including the Prolift System, have demonstrably worse improvement in their quality of life (QOL) over traditional, non-mesh repair.



3. Overall, patients implanted with non-absorbable, transvaginal synthetic mesh for pelvic organ prolapse, including the Prolift System, do not have demonstrable improvement in reoperation rates over traditional, non-mesh repair.
4. The increased patient risks, complication rates, and the added expense of the Prolift System far outweigh any stated or implied benefits.
5. There was no need for the Prolift System, a non-absorbable, synthetic mesh, to be sold and marketed as a surgical treatment and procedure for pelvic organ prolapse (POP) as there were safe, effective and reasonable alternative surgical treatments available at the time this product was launched that did not needlessly endanger patients nor carry the likelihood or risk of serious injury that has been associated with the Prolift System. Accordingly, the Prolift System should have never been marketed to surgeons or patients in the first place, and I agree with Ethicon's 2012 decision to cease marketing the Prolift System for use in the United States.

#### **B. Complication Rate**

1. Synthetic transvaginal meshes for POP, including the Prolift System, subject patients to needless danger through increased risks not present in traditional, non-mesh surgery for POP repair. Prolift has, therefore, caused serious and potentially permanent injuries due to complications associated with its implantation for POP repair.
2. Even when surgeons used the Prolift System as designed and marketed, it was unsafe to patients for its intended use as a method of surgical POP repair because of patient-to-patient anatomic variability and surgeon-to-surgeon variability in experience, training and technique, as well as the inherently unsafe characteristics of the procedure and mesh.
3. Because non-absorbable, synthetic, polypropylene mesh such as Prolift causes an intense foreign body reaction in pelvic tissue, there is no way to safely implant these products into a woman's pelvic tissue without an increased risk of serious complications including, but not limited to, pain associated with the implant procedure (including but not limited to nerve, vascular, organ and tissue damage), chronic pelvic pain associated with fibrosis and scarring, adhesions, vaginal retraction and shortening, fistula formation, granuloma formation, chronic infection associated with, among other things, the product's implantation into a clean/contaminated field and the intense inflammatory response to the polypropylene, chronic wound healing issues, organ erosion, vaginal extrusion/exposure, chronic pelvic pain associated with the explant procedure (including but not limited to nerve, vascular, organ and tissue damage), de novo incontinence, significant dyspareunia (painful intercourse), and the lack of a safe and effective method to treat the complications, including the removal of the mesh when necessary.

### **C. Data Withheld From Physicians**

1. Ethicon failed to completely disclose to physicians and their patients the known risks of prolapse surgery using Prolift. By withholding this information and failing to provide adequate warnings and/or instructions, Ethicon failed to act as a reasonably prudent medical device manufacturer. Because of its actions, Ethicon knowingly exposed patients to needless, preventable danger, harm and permanent suffering. Ethicon's failure to disclose risks known to it about the Prolift took away physicians' ability to properly and appropriately consent their patients.
2. Ethicon failed to disclose the lack of benefit of POP surgery using the Prolift System to physicians and patients. By withholding this information and failing to provide adequate warnings and/or instructions, Ethicon failed to act as a reasonably prudent medical device manufacturer and thereby exposed patients to needless danger and harm.
3. Ethicon inadequately informed physicians and their patients that the Prolift System caused significant risks to normal sexual activity. Specifically, Ethicon made a conscious decision not to include statements regarding the likelihood that undergoing a POP surgery utilizing the Prolift System could cause "pain with intercourse and pelvic pain," and because of these misrepresentations, countless women will permanently and needlessly be forced to suffer lifelong pain and embarrassment.

### **D. Breach of Duty by Ethicon**

1. Ethicon breached its duty of reasonable care to implanting surgeons and to patients by marketing and selling Prolift Pelvic Floor Repair Systems as a "revolutionary" surgical device and procedure without sufficient evidence to support the Prolift System's safety, effectiveness and benefit, and with specific knowledge of the increased risks of non-absorbable, synthetic surgical mesh for POP, including its product, Prolift.
2. Ethicon breached its duty of reasonable care to implanting surgeons and to patients by marketing and selling the Prolift System (both the product and the procedure) to surgeons and patients without proper warnings, proper training, without proper instructions for use and without sufficient evidence of its safety and efficacy, thereby exposing patients to needless danger and unreasonable risk of harm.
3. Ethicon breached its duty of reasonable care to implanting surgeons and to patients by failing to timely disclose its knowledge of a significant increase in complications associated with the Prolift System even though it had the ability to do so through physician communications, "Dear Surgeon" letters, its sales force, sales and marketing brochures to physicians and patients and/or updates to its Instructions for Use to physicians, and in fact used those means of communications to minimize the impact of risk information when it was brought to light through other sources.

#### **IV. NORMAL ANATOMY AND PELVIC ORGAN PROLAPSE**

The normal vagina is a functional, pliable, distensible, mobile, and well-supported structure. Pelvic organ prolapse (POP) is a condition in which one or more of the female pelvic organs (bladder, rectum, uterus, and/or intestines) drop into the vagina to varying degrees, as a result of weakened vaginal tissue to form a bulge or fullness in the vagina. POP can affect the quality of life (QOL) of women; however, POP is not a life-threatening condition. POP is for many women a normal part of the aging process and can result from some combination of increasing age, multiple childbirths, frequent heavy lifting, chronic cough, obesity, constipation, previous hysterectomy and genetic predisposition. Symptoms of POP are usually limited to QOL issues such as the sensation of pelvic fullness, pressure and interference with sexual activity. It can also impact on urination and bowel function. POP is a relatively common condition, with up to 50% of women who have had children having some degree of POP; however, only a fraction of those women are symptomatic. Medical device manufacturers such as the manufacturer of the Prolift, Ethicon, perceived that the potential surgical market created a desirable target for device manufacturers eager to capture market share. (Wall L: The perils of commercially driven surgical innovation. *Am J of Obstetrics and Gyne* Jan 2010; 202.30e1-4).

As mentioned above, POP is a protrusion or a falling down of one or more of the pelvic organs into the vagina. This can affect one or more of the vaginal “compartments.” These compartments are:

1. The bladder (called an Anterior Compartment Prolapse or Cystocele).
2. The rectum (called the Posterior Compartment Prolapse or Rectocele).
3. The uterus (called Uterine Prolapse).
4. The small intestines (called the Apical Compartment Prolapse or Enterocele).
5. In cases where POP affects all of the compartments, this is often referred to as a Vaginal Vault Prolapse.

Treatment for female pelvic organ prolapse can be generally broken down into four main categories:

1. Behavior modification & Pelvic Floor Therapy & Exercises
2. Medication
3. Pessary
4. Surgical treatment

#### **V. TREATMENT**

##### **A. Traditional POP Treatment Options**

There are multiple well-established treatment options for treating POP. A thorough understanding of the risks and benefits of each of the POP treatment options is imperative for the treating physician to evaluate and recommend appropriate therapy for each patient since each patient represents unique characteristics, symptoms, and risk factors, which can affect the success and complications of any therapy. Following a thorough physical exam by a trained

medical practitioner, the severity and QOL impact of the POP is determined. Management options of POP can be broken down into several broad categories such as observation, behavioral therapies, pelvic floor exercises, pessary use, and, as a last resort, surgery. Since POP is primarily a QOL issue, the physician must first determine whether or not the POP is actually problematic for the patient. Many times the POP is mild and causes either no or only minimal symptoms. In this frequent situation, the safest treatment option is observation with periodic reevaluation to determine if the POP and the patient's symptoms progress or not. For the patient with POP that is symptomatic, further conservative options can be considered such as behavioral changes (weight loss, lifestyle changes), pelvic floor exercises and/or the use of pessary devices.

Surgical procedures should usually be reserved for severe, high grade POP that is negatively impacting the QOL for the woman. Surgical repair of POP has been documented and has evolved over the years. Traditional surgery is performed from either the vagina (termed "transvaginal") or from the abdomen (termed "transabdominal"), with the latter group being performed either with an abdominal incision (Abdominal Sacrocolpopexy) or with minimally-invasive procedures such as with laparoscopic or robotic technology. The Prolift procedure was developed as an alternative procedure to the traditional methods of treating prolapse. By definition, a comparison of the safety and effectiveness/risks and benefits of the Prolift with the alternatives requires a comparison with these traditional procedures.

#### **B. Traditional, Transvaginal NON-Mesh POP Procedures**

Traditional transvaginal surgery for POP utilizes an incision through the wall of the vagina hence the term "transvaginal" literally meaning "through the vagina." It is imperative to recognize the basic difference between transvaginal and transabdominal (through the abdomen) surgery since the surgical route chosen affects success, complications, and QOL results.

Traditional non-mesh transvaginal surgery relies on the mobilization and the stitching together of the patient's own deep vaginal tissues (also known as "native tissue") to support the vagina and to repair the POP. Traditional transvaginal surgery for POP, in contrast to Prolift Pelvic Floor Repair Systems, does NOT utilize the blind passage of trocars or mesh in its repair.

One of the most significant arguments used by mesh manufacturers to justify vaginal mesh use over the traditional, non-mesh POP repairs was the misconceived notion that traditional repairs had failure rates of up to 30-40%. This failure rate was based primarily on the work of the 2001 National Institutes of Health (NIH) Workshop on Standardization of Terminology for Researchers in Pelvic Floor Disorders. However, since the Workshop's recommendations in 2001, there have been significant advancements in the understanding of what is normal vaginal support, pelvic prolapse, POP symptoms, and the very critical issue of what patients perceive as a successful outcome following POP surgery. What is now apparent is that the NIH POP Workshop grading system was so strict that a large percentage of average healthy women would fail if graded under that system. This misconception has now been recognized in the medical literature. Currently, within contemporary POP studies which utilize up-to-date prolapse

definitions, the accepted failure rate of traditional, non-mesh POP repairs is less than 15% and closer to 12%.<sup>1 2 3</sup>

### C. Transabdominal/Laparoscopic/Robotic POP Repair

Sacrocolpopexy is a procedure performed through the abdomen. Although not without risk, sacrocolpopexy is superior to transvaginal mesh procedures as it offers a greater chance of long-term anatomical and symptomatic POP success, with fewer risks. Traditionally, this approach utilized an incision in the lower abdomen. However, with the advancement of minimally invasive procedures such as laparoscopy and robotic surgery, the procedure is increasingly performed using these less invasive alternatives. The procedure entails stitching a mesh or biomaterial to the top, apex and bottom of the vagina then stitching that same mesh or biomaterial to the large bones at the base of the spine called the sacrum.

### D. History of Synthetic Mesh

Abdominal and thoracic wall weaknesses, called hernias, exist due to inherent weaknesses within the abdominal wall or thoracic wall due to conditions such as birth defects, surgery, and radiation effects. Traditional hernia repair surgery evolved using sutures (stitches) to bring the native tissue together. However, due to the inherent weaknesses of the tissues, failure was common and frequently resulted in significant pain and suffering for the patient. Therefore, in the 1950's, surgical meshes for hernia repairs were introduced. Subsequently, academic presentations, surgical reports and journal manuscripts began to describe mesh-related complications such as chronic pain, abdominal wall rigidity, mesh contraction, infection, fistula formation, recurrence and chronic inflammatory process.<sup>4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22</sup>

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<sup>1</sup> Weber AM, Walters MD, Peidmonte MR et al: Anterior Colporrathy: A randomized trial of three surgical techniques. Am J Obstet Gynecol (2001) 185(6):1299-304; discussions 1304-6. 172

<sup>2</sup> Weber AM, Abrams P, Brubaker L: The standardization of terminology for researchers in female pelvic floor disorders. Int Urogynecol J (2001) 12:178-186

<sup>3</sup> Chmielewski L, Walters MD, Weber AM, et al: Reanalysis of a randomized trial. J ObstetGynecol (2011) 205:96.e1-8

<sup>4</sup> Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan;2(1):103-17.

<sup>5</sup> Agresta F, Baldazzi G, Ciardo et al: Lightweight partially absorbable monofilament mesh (polypropylene/poliglecaprone 25) for TAPP inguinal hernia repair. Surg laparosc endosc percutan tech 2007, 17;91-94.

<sup>6</sup> Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. Hernia (1997) 1:15-21.

<sup>7</sup> Bellon J, Honduvilla N, Jurado F et al: In vitro interaction of bacteria with polypropylene/ePTFE prostheses. Biomaterials. 2001 Jul;22(14):2021-4.

<sup>8</sup> Bouikerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. European J. Obstet & Gynecol and Repro Bio 134: (2007)262-267.

<sup>9</sup> Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998.

<sup>10</sup> Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul;165(7):665-73.

<sup>11</sup> Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002).



An abundant amount of evidence in the medical literature and basic science data has been gathered over the past two decades that indicates that there is a strong and direct relationship between postoperative mesh complications and mesh design.<sup>23 24 25 26 27 28 29 30 31 32 33</sup> Reducing mesh-related complications demands a thorough understanding and knowledge of the chemical, physical and synthetic characteristics of meshes and how they react inside the human body. Based upon vast amounts of general surgery and basic science literature, there is a consensus that synthetic meshes that are lower weight (less surface area), larger pore size, higher porosity, monofilament, and that are capable of maintaining their elasticity and structural stability during and after implantation will have better results with fewer complications. Of all the mesh characteristics, pore size and stability of the mesh are among the most important.

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<sup>12</sup> Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. *Biomaterials*. 1998 Dec;19(24):2235-46.

<sup>13</sup> Krause H, Galloway S, Khoo S et al: Biocompatible properties of surgical mesh using an animal model. *Aust N Z J Obstet Gynaecol*. 2006 Feb;46(1):42-5.

<sup>14</sup> Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. *Int Urogynecol J*. 2011 Jan;22(1):47-52.

<sup>15</sup> Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. *American Journal of Surgery* Vol 193, Issue 4, April 2007, p538-542.

<sup>16</sup> Cappelletti M, Attolini G, Cangioni G, et al. The use of mesh in abdominal wall defects. *Minerva Chir*. 1997 Oct;52(10):1169-76.

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## **E. Synthetic Mesh Use in Urogynecology**

### **1. Sacrocolpopexy**

Synthetic meshes are used transabdominally in sacrocolpopexy. Sacrocolpopexy can now be performed using laparoscopic and robotic technologies. Although mesh is used in sacrocolpopexy, there are important distinctions between the two procedures. As explained above, the mesh used in sacrocolpopexy is inserted through the sterilized transabdominal approach whereas in the transvaginal procedure, the mesh passes through the “*clean contaminated*” environment of the vagina and therefore is exposed to bacteria and other pathogens during and after implantation.

The amount of mesh used in sacrocolpopexy is significantly less than that typically used in the Prolift System and other transvaginal mesh POP repair procedures. The anatomical location of the mesh and the forces applied to the mesh during implantation also differ between the two procedures. In sacrocolpopexy, the mesh does not need to be inserted through the use of cannulas and is therefore much less likely to experience folding or roping during insertion. Unlike transvaginal procedures, which are done blindly through the use of trocars, sacrocolpopexy allows the surgeon to visualize the placement of the mesh, which avoids the risks of blind passage. For all of these reasons, the risk profile of sacrocolpopexy is superior to that of transvaginal mesh kits for POP, including the Prolift System.

### **2. Transvaginal Mesh Kits for POP**

Use of transvaginal synthetic mesh for POP repair was marketed mainly as a way to increase the durability of the POP repair relative to the misperceived higher failure rate of traditional, non-mesh transvaginal POP surgery. A brief comparison is warranted between the traditional, transvaginal non-mesh POP surgery and the prepackaged mesh kits in order to understand the new and unique treatment alternative the mesh kits represented upon their introduction to the marketplace. The general similarities between traditional, transvaginal and mesh kit POP procedures are:

- Both are designed to treat POP;
- At the time of surgery, the patient is placed in the same position on the operating table;
- The procedures are done under either general or spinal anesthetic;
- The procedures are performed through the vagina; and,
- A cystoscopy is required when performing an anterior or apical repair to rule out inadvertent bladder injury.

Traditional non-mesh transvaginal POP surgery diverges from mesh kit procedures at this point. Typically, traditional surgery, instead of using a synthetic mesh to hold up the prolapsing pelvic organ, uses only sutures (also called stitches) placed into the native tissues surrounding the prolapsing portion of the vagina to repair the POP. These stitches are placed under direct

vision, meaning the surgeon can visualize where the stitch is going, thereby reducing the risk of injury to surrounding tissues and pelvic organs.

In general, there are several broad, though very important differences between traditional, transvaginal non-mesh and mesh kit POP surgeries:

- No synthetic, non-absorbable meshes are used in traditional POP surgery;
- No trocars/guides are used to place the mesh into position in traditional POP surgery;
- There is no tensioning of mesh arms with traditional surgery, and;
- The traditional procedure is performed under direct vision, meaning that the surgeon can see what he/she is doing with no blind passing of trocars.

## VI. ETHICON MESH

### A. Prolene Mesh

Ethicon first developed sheets of Prolene mesh that could be cut to a desired shape by surgeons, for the surgical treatment of hernias. Shortly thereafter, the same mesh became available for use as the Prolene Hernia System, which is described as a sterile, pre-shaped three-dimensional patch constructed of an undyed Prolene polypropylene mesh constructed of knitted, non-absorbable polypropylene monofilaments identical to those used in Prolene polypropylene nonabsorbable surgical sutures manufactured by Ethicon. Ethicon has reported that this material, when specifically used as a suture (stitch), is nonreactive and retains its strength indefinitely. The Prolene sheets and Prolene Hernia Systems were introduced in the 1990's and were designed and *"... indicated for the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result."*

As early as 2000, Ethicon employees understood the importance of mesh characteristics, including the importance of pore size and its relation to tissue incorporation. Yet, despite this information, the pore sizes of the Prolene Soft Mesh vary significantly within the mesh. Ultimately, Ethicon stated that the pore sizes (in area) for the Prolene Soft Mesh ranged somewhere between 0.29 mm<sup>2</sup>, 0.34 mm<sup>2</sup>, 1.08 mm<sup>2</sup>, 1.29 mm<sup>2</sup>, 1.70 mm<sup>2</sup>, and 2.38mm<sup>2</sup> before implantation in the body; but according to Ethicon employees, Ethicon never measured the diameters of the various pores of the Prolene Soft mesh either before or after stretch.<sup>34</sup>

### B. Gynemesh Prolene Soft (Gynemesh PS)

In 2000, Ethicon received 510(k) clearance from FDA to market and sell Prolene Soft Mesh, sheets of lighter-weight Prolene that could be cut to a desired shape by surgeons for the surgical treatment of hernias. The stated intended use of Prolene Soft Mesh was for repair of *"abdominal wall hernias or other fascial defects that require additional reinforcing or bridging material for adequate repair"*. The mesh is constructed of knitted filaments of polypropylene

<sup>34</sup> Burkley Depo 10/2/2012 and exhibits thereto



identical in composition to those used in Prolene polypropylene, nonabsorbable surgical sutures manufactured by Ethicon. The mesh was reported to have been constructed of reduced diameter monofilament fibers, knitted into a unique design which resulted in a mesh that was approximately 50% more flexible than standard Prolene mesh. The Prolene Soft 510(k) document mirrors the language from Prolene by stating “*this material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use.*”

Prolene Soft construction was reported as being knitted by a process, which interlinks each fiber junction, which will provide for elasticity in both directions (*bi-directional*).<sup>35,36,37,38,39,40</sup> This stated “*bi-directional*” elastic property, if accurate, would theoretically allow the mesh to adapt and move so as to accommodate the various stresses encountered in the body. Ethicon documents indicate that this stated bi-directional elastic property would appeal to implanting physicians when choosing the most appropriate treatment option for their patients given the dynamic nature of the female pelvis.

In 2002, Ethicon received 510(k) clearance of Gynemesh Prolene Soft Mesh (Gynemesh PS) which is the exact same mesh as Prolene Soft Mesh. Nonclinical laboratory testing was not performed on the Gynemesh PS product since Ethicon took the position that felt there was no change in the intended clinical use (abdominal wall hernia repair and other fascial defects) when compared to the predicate devices. The mesh is stated to have been designed to provide maximum strength, durability, and surgical adaptability with sufficient porosity for necessary tissue ingrowth.<sup>41</sup> It has been well documented that mesh characteristics and qualities are paramount for successful outcomes.<sup>42,43,44,45,46,47,48,49</sup> With this knowledge, Ethicon inaccurately advertised that Gynemesh PS had “*Large pore size [which] fosters tissue incorporation.*”<sup>50</sup>

Published clinical data on the use of Prolene Mesh and Mersilene mesh was submitted to support the use of these materials as reinforcing or bridging materials in fascial deficiencies of the pelvic wall. Gynemesh PS (identical to Prolene Soft Mesh) was marketed heavily by Ethicon

<sup>35</sup> ETH.MESH.00015699 - 00015706

<sup>36</sup> ETH.MESH.00013506

<sup>37</sup> Walji Deposition p. 471-472

<sup>38</sup> Robinson Deposition 3-14, p. 683-684

<sup>39</sup> Kirkemo Deposition 4-18, p.246-247

<sup>40</sup> Ciarroca Deposition 3-29, p.264

<sup>41</sup> ETH.MESH.00797 - 00927

<sup>42</sup> Robinson Deposition 3-13, p. 129

<sup>43</sup> Kirkemo Deposition 4-18, p.125-131

<sup>44</sup> de Tayrac R, Gervaise A, Chauveaud A et al: Tension-free polypropylene mesh for vaginal repair of anterior vaginal wall prolapse. J Reprod Med. 2005 Feb;50(2):75-80.

<sup>45</sup> de Tayrac R, Picone O, et al. A 2-year anatomical and functional assessment of transvaginal rectocele repair using a polypropylene mesh. Int Urogynecol J (2006) 17: 100-105.

<sup>46</sup> Milani R, Salvatore S, Soligo M, et al. Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh. BJOG. 2005 Jan;112(1):107-11.

<sup>47</sup> Ganj F, Ibeanu O, Bedestani A et al: Complication of transvaginal monofilament polypropylene mesh in POP repair. Int Urogynecol J Pelvic Floor Dysfunct. 2009 Aug;20(8):919-25. Epub 2009 Apr 7.

<sup>48</sup> Carey M, Higgs P. Vaginal repair with mesh vs colporrhaphy for prolapse a randomized controlled trial. BJOG. 2009 Sep;116(10):1380-6.

<sup>49</sup> Collinet P, Belot F, Debodinance P et al. Transvaginal mesh technique for pelvic organ prolapse repair: mesh exposure management and risk factors. Int Urogynecol J (2006)17:315-320.

<sup>50</sup> ETH-00253

to gynecologists, urologists and urogynecologists as a mesh “*uniquely*” designed and “*Technically advanced by design*” and “*uniquely permanent...*” to meet the needs of POP repair surgery.

In March of 2005, Ethicon launched its first pelvic floor repair kit, Prolift. Ethicon marketed and sold Prolift in the United States for more than three years without obtaining clearance by the FDA. At the demand of FDA, Ethicon subsequently submitted its 510(k) pre-market notification application to FDA seeking permission to sell and market Prolift in the United States.

In May of 2008, more than three years after Ethicon began marketing Prolift, they received 510(k) clearance for both Prolift and Prolift +M. The Prolift kit uses Prolene Soft Mesh (intended for hernia repair) and the Prolift+M kit uses Ultrapro (intended for hernia repair).

### **C. Prolift Pelvic Floor Repair System**

#### **1. General Product Descriptions**

The use of transvaginal synthetic mesh for POP repair through the Prolift procedure was marketed by Ethicon primarily as a way to increase the durability of the POP repair relative to the misperceived and grossly exaggerated “higher” anatomic recurrence rates of traditional, non-mesh transvaginal POP surgery. In point of fact, this foundational premise for the marketing of this device was based on several significant items of misinformation. First and foremost, reliance on anatomic recurrence rates as the basis for evaluating the success or failure of a prolapse repair procedure is not valid. The issue is whether or to what extent a recurrence is symptomatic or, in other words, affects the quality of life of the woman. For example, stage 2 prolapse after a prolapse repair is considered to be an anatomic recurrence and technical failure, yet the overwhelming majority of women with such a recurrence following native tissue repair do not feel the need for further treatment, let alone surgery. Thus, the marketing of the Prolift as a means to reduce anatomic recurrence rates completely missed the point. Unfortunately, this marketing strategy was quite successful with surgeons, and ultimately, even AUGS in Committee Opinion 513 acknowledged that functionality and quality of life must be the touchstone.

Second, Ethicon’s studies of the mesh material and the prototype procedure in the Gynemesh PS and TVM studies, respectively, demonstrated anatomic recurrence rates as high as or higher than those reported in the studies selectively chosen and miscited by Ethicon in its effort to establish that the recurrence rates with the traditional procedures were unacceptably high. The recurrence rates in the French TVM study exceeded the 20% recurrence rate (at a one-sided 95% confidence interval) pre-determined by Ethicon to be the bright line cut off for success or failure of the procedure. Pursuant to the internal protocols governing the development of the procedure, this was supposed to result in not marketing the procedure; however, Ethicon simply ignored its own protocol and marketed the Prolift. Parenthetically, this is not an isolated failure to adhere to internal protocols put in place to assure that the procedure was safe and effective and that the risks were outweighed by the benefits. Rather, this is part of a disturbing pattern of ignoring such protocols, including the failure to return the project to the concept phase when it was established at least as early as 2003 that erosion and contraction, as well as

recurrences, were resulting from the mesh material (a litany of documents demonstrate that Ethicon was aware of these problems, and knew that the mesh material was not safe and effective and needed to be replaced as soon as possible per internal scientists like Gene Kammerer and Joerg Holste and the inventors of the procedure Dr. Michel Cosson and Prof. Bernard Jacquetin). In fact, many emails and internal documents show that Ethicon was investigating the use of partially absorbable Ultrapro mesh as a means to reduce sexual function issues and other complications, even before the time the Prolift went to market.

Another example is the complete failure to evaluate all potential risks and complications, and the consequences thereof, as part of the pre-launch design control process, which both Dr. Piet Hinoul and Dr. James Hart have confirmed invalidates that FDA mandated process, and thus, should have required that the Prolift not be marketed. Another example is the failure by Dr. Charlotte Owens to conduct a proper pre-launch evaluation of the Prolift, including but not limited to the failure to prepare an original, heavily-researched and objectively-executed clinical evaluation and clinical expert report, which was yet another requirement before marketing that was ignored.<sup>51</sup>

The Prolift was never adequately studied before or after launch. Due to the novel procedure and the unknown risks of this method of placement of the mesh material, the system should have been investigated as an experimental procedure, at most, and not marketed. In fact, internal documents and the deposition of Price St. Hilaire demonstrate that Ethicon worked “behind the scenes” to get ACOG to revise a February 2007 Practice Bulletin that deemed this and similar procedures to be experimental, deleting the reference to experimental due to concerns over insurance and other payor reimbursements for the surgery. This level of documented manipulation of an important medical society is quite disturbing.<sup>52</sup>

The lack of adequate clinical studies is exemplified by the ultimate withdrawal of the Prolift from the market, which Ethicon clearly stated to the FDA was not a reaction to the risks and lack of safety, but rather a “business decision.” The internal documents and deposition of Brian Kanerviko prove that the reason the Prolift was withdrawn from the market was because Ethicon faced a choice of conducting the type of robust clinical study that would have shown just how deficient and unsafe the procedure was, or withdraw the Prolift. In fact, this option was apparently first considered on the day Ethicon received the FDA’s 522 order requiring the studies be performed. In this context, the FDA rejected the two RCT’s presented by Ethicon as insufficient to prove safety and effectiveness. Rather than performing new studies or submitting different studies to satisfy the FDA’s 522 Orders, Ethicon withdrew the Prolift from the market. In short, to date, Ethicon has never submitted studies that the FDA deemed sufficient with respect to the Prolift.<sup>53</sup>

Prolift represents a major departure from the traditional, non-mesh transvaginal POP surgeries. Prior to the marketing of the Prolift, Ethicon marketing executive Steve Bell explained in an email he wrote after attending the first demonstration of the procedure to interested physicians, that performance of the Prolift procedure would require a “major mind

<sup>51</sup> Piet Hinoul Depos 4/5-4/6/12, 9/18-9/19/12, 6/26-6/27/13, 1/13/14 & 1/15/14 and exhibits thereto, James Hart Depo 9/17-9/18/13 and exhibits thereto, Charlotte Owens depo 9/12-9/13/12 & 6/19-6/20/13 and exhibits thereto]

<sup>52</sup> Price St. Hilaire depo 7/11-7/12/13 and exhibits thereto]

<sup>53</sup> Brian Kanerviko depo 8/22-8/23/13 and exhibits thereto]

shift,” based on the differences with the surgeons’ training and experience.<sup>54</sup> In contrast to traditional non-mesh surgery, the Prolift Pelvic Floor Repair System represents a newly described, “revolutionary” surgical technique and, according to the patient brochure, was a complete surgical system for the treatment of all aspects of POP. The Prolift Pelvic Floor Repair System comes to the surgeon as a self-contained kit, complete with surgical instruments, uniquely cut synthetic (hernia) meshes, the procedure, and the IFU containing the purported indications, contraindications, warnings, adverse reactions, and information about how to perform the procedure. There are three separate kits, each designed to treat a specific type of POP:

1. Gynecare Prolift Anterior Pelvic Floor Repair System -- for repair of bladder prolapse (cystocele)
2. Gynecare Prolift Posterior Pelvic Floor Repair System -- for repair of rectum prolapse (rectocele)
3. Gynecare Prolift Total Pelvic Floor Repair System -- for repair of cystocele, rectocele, and vaginal vault prolapse

Each kit is similar except for the shape of the mesh and varying number of surgical components used for inserting and retrieving the mesh into and from the patient’s vagina and pelvis. (Fig. 1) Each kit also contains a uniquely made, pre-cut designed to repair a specific compartment of the vagina (Fig. 2).

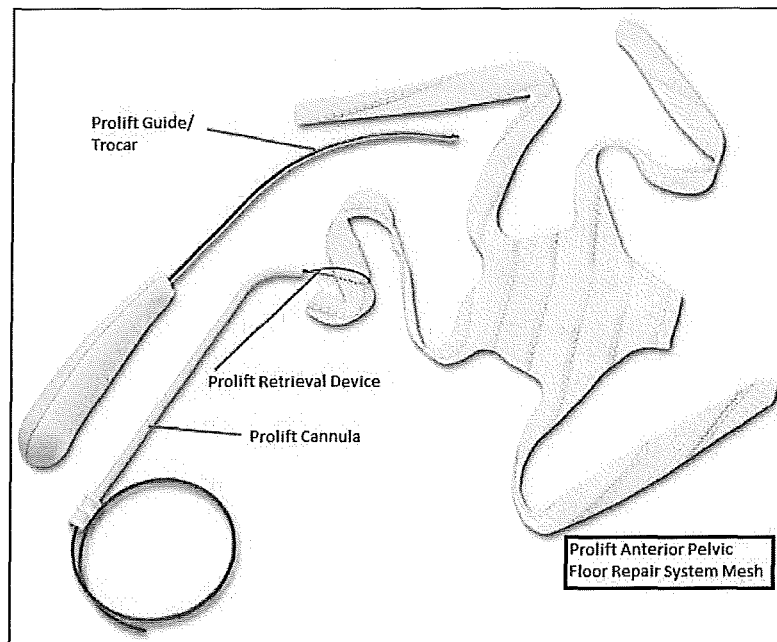


Fig. 1

<sup>54</sup> ETH.MESH.02282833

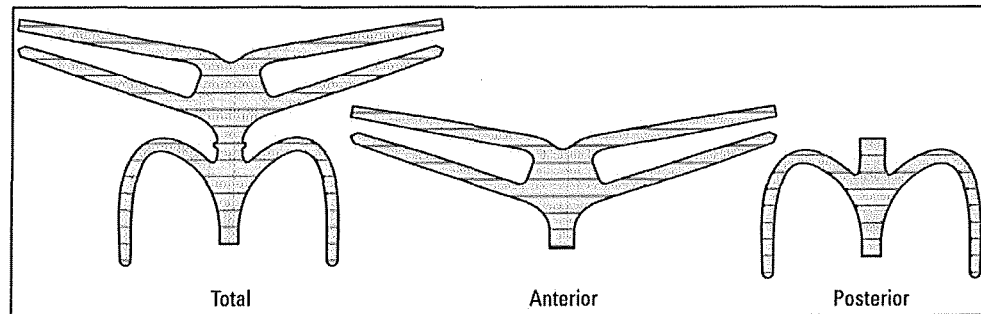


Fig. 2

Each Prolift System kit contains pre-cut mesh composed of non-absorbable knitted filaments of polypropylene identical in composition to those used in Prolene polypropylene, nonabsorbable surgical sutures manufactured by Ethicon. The mesh is reported to have been constructed of reduced diameter monofilament fibers that are knitted into a unique design which resulted in a mesh that is reported to be approximately 50% more flexible than standard Prolene mesh. The Prolift mesh is of identical composition and manufacturing as the Gynemesh PS and Prolene Soft Mesh marketed by Ethicon for use in hernia repair. However, contrary to Prolene Soft Mesh, Prolift meshes were intended to be used for vaginal tissue reinforcement and stabilizations of the fascial structures of the female pelvic floor in vaginal wall prolapse (POP).

Each Prolift System comes with a Performance claim stating that the “*Gynemesh PS elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.*”

## 2. Prolift Pelvic Floor Repair Systems Components

Along with the synthetic mesh, each kit contains a Prolift Guide/trocar, varying numbers of Prolift Retrieval Devices, and Prolift Cannulas. Each component of the Prolift System is unique and specific to the Prolift Pelvic Floor Repair System.

### a) Prolift Guide

The Prolift Guide, also referred to as a “trocar” (Fig. 3) is a single patient, single use surgical instrument specifically designed to create tissue paths to allow the positioning of the meshes of the Prolift Anterior, Prolift Posterior, and Prolift Total. It also is used to facilitate the placement of the Prolift Cannula. Its specific shape, length, design, and curvature were specifically constructed to be used solely with the Prolift and meshes.



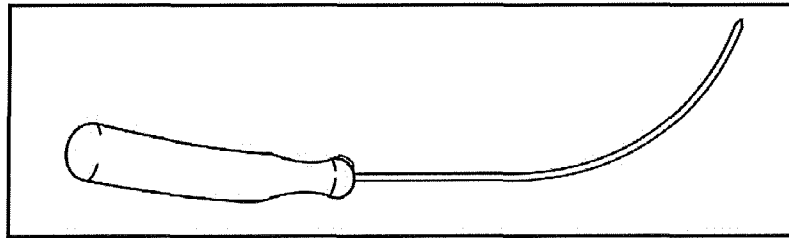


Fig. 3: Prolift Guide

***b) Prolift Cannula***

The Prolift Cannula (Fig. 4) is a single patient, single use surgical instrument specifically designed to be used in conjunction with the Prolift Guide/trocar to facilitate passage of the Prolift mesh straps in an effort to reduce damage to the surrounding vaginal tissues and pelvic organs. Each Prolift Cannula is placed over the trocar prior to passage and remains in place until after the trocar is removed. The Prolift Cannula's specific shape, length, design, and curvature were specifically constructed to be used solely with the Prolift.

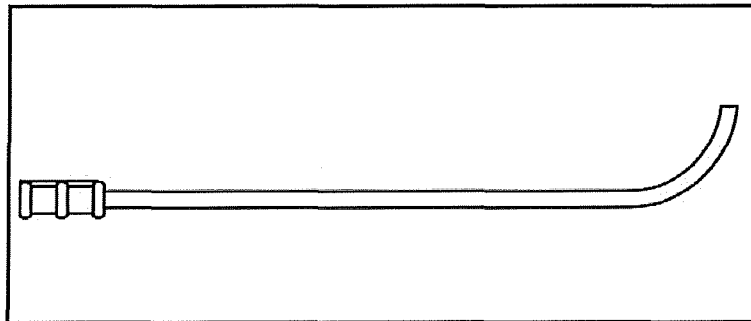


Fig. 4: Prolift Cannula

***c) Prolift Retrieval Device***

The Prolift Retrieval Device (Fig. 5) is a single patient, single use surgical instrument specifically designed to be used with the Prolift Pelvic Floor System. The Retrieval Device is passed through the previously placed Prolift Cannula until its farthest most end is passed into and through the vaginal dissection area. The farthest most end of the Retrieval Device has a loop to securely fix the mesh implant straps as the strap is withdrawn through the Prolift Cannula. The Retrieval Device's specific shape, length, and design were specifically constructed to be used solely with the Prolift Systems.

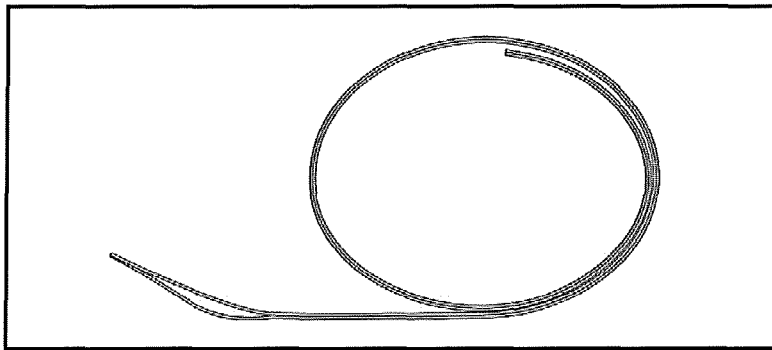


Fig. 5: Prolift Retrieval Device

All the components of the Prolift Pelvic Floor System are packaged so as to be used together, in combination, and not with any other pelvic floor repair kit. The three separate kits (Prolift Anterior, Posterior and Total) and their individual kit variations are briefly outlined below:

***d) Prolift Anterior Pelvic Floor Repair System***

The Anterior mesh implant (Fig. 2) is constructed of Gynemesh PS and is pre-cut for surgical repair of anterior vaginal wall prolapse (cystocele). The implant has four straps, which are placed and fixed in position via multiple blind Prolift trocar passes through the transobturator route. Each of the pre-cut extension arms of the mesh is designed to permanently reinforce the pubocervical fascia.

The Prolift Anterior Pelvic Floor Repair System kit comes with an included Prolift Guide/trocar (Fig. 2), four Prolift Cannulas (Fig. 3), and four Prolift Retrieval Devices (Fig. 4).

***e) Prolift Posterior Pelvic Floor Repair System***

The Posterior mesh implant (Fig. 2) is constructed of Gynemesh PS and is pre-cut specifically for repair of the posterior and possibly apical vaginal wall prolapse. The mesh is configured so as to have two straps that are secured into place with blind trocar passages through the sacrospinous ligament via a transgluteal (buttock) approach or modified to be placed via a vaginal approach. Each of the pre-cut extension arms of the mesh is designed to permanently reinforce the rectovaginal fascia.

The Prolift Posterior Pelvic Floor Repair System kit comes with an included Prolift Guide/trocar (Fig. 2), two Prolift Cannulas (Fig. 3), and two Prolift Retrieval Devices (Fig. 5).

***f) Prolift Total Pelvic Floor Repair System***

The Total mesh implant (Fig. 2) is constructed of Gynemesh PS and is pre-cut specifically for surgical repair of total vaginal vault prolapse. The implant has six straps; four used for securing the anterior (top) portion of the mesh via blind trocar passage using the transobturator route and two for securing the posterior (bottom) portion of the mesh into the sacrospinous ligament via blind trocar passage using the transgluteal (buttock) route.

The Prolift Total Pelvic Floor Repair System kit comes with an included Prolift Guide/trocar (Fig. 3), six Prolift Cannulas (Fig. 4), and six Prolift Retrieval Devices (Fig. 5).

### **3. Surgical Technique**

One of the unique characteristics of the Prolift Pelvic Floor Repair Systems compared to traditional, non-mesh POP surgeries is that the Prolift Systems are a self-contained surgical “kits” *and* procedures. Prolift Systems is purchased as a complete, packaged entity (kit) complete with a uniquely shaped, pre-cut synthetic, nonabsorbable mesh, varying numbers of Prolift Guides/trocars, Prolift Cannulas, and Prolift Retrieval Devices *and* a Prolift Surgical Guide and IFU.

#### ***a) Prolift Anterior Pelvic Floor Repair Procedure***

Ethicon maintains that in order to reduce complications, to provide the most appropriate anatomical results, as well as to maintain normal vaginal and pelvic floor function, it is imperative for the mesh arms once surgically inserted to be “*tensioned appropriately*”. However, it should be noted that there is no standardized method of measuring “*tension*.” By definition, due to the weight of pelvic organs, once the patient is standing, the mesh will no longer be “*tension-free*”. Also by definition, the Prolift arms are tensioned from the moment they are implanted and fixed and they begin to compensate for the pelvic forces that the damaged native tissue can no longer compensate for.

#### ***b) Prolift Posterior Pelvic Floor Repair Procedure***

As with the Anterior Prolift mesh, the appropriate positioning of the mesh, “without tension”, is necessary. Ethicon knew that, with this procedure, the surgeon may trim the mesh based upon the specific needs of the patient.

#### ***c) Prolift Total Pelvic Floor Repair Procedure***

The Prolift Total Pelvic Floor Repair System entails a combination of both the Prolift Anterior and the Prolift Posterior procedures with variations of each making the Prolift Total a unique procedure. Also, the surgeon must make varying perioperative decisions dependent upon whether or not the patient has a uterus and whether or not a hysterectomy is going to be performed at the time of the Prolift Total procedure. The Prolift Total mesh (Figure 2) is supposedly uniquely shaped and specifically designed to address a total vaginal vault prolapse. However, the surgeon must cut the mesh depending on whether the patient has or has not had a previous hysterectomy and whether uterine preserving surgery is to be performed. These are all decisions the experienced surgeon would address preoperatively with the patient. In order to place the Prolift Total Pelvic Floor Repair System, first the Prolift anterior procedure is performed and then, the Prolift posterior procedure is performed. This would leave a total of 6 incisions. As with the Prolift Total Pelvic Floor Repair System, the Prolift Anterior Pelvic Floor Repair System, and the Prolift Posterior Pelvic Floor Repair System, the trocars are passed blindly and can result in serious patient injury. Lastly, the surgeon is then faced with the challenge of attempting to appropriately tension the mesh arms in order to reduce the risk of complications.



#### 4. The Prolift System Constitutes Major Invasive Surgery

The insertion technique for the Prolift System is a complicated one and, even in the hands of the most careful and highly-skilled surgeon, significant complications for the patient can occur. Moreover, there can be little doubt that the implantation of the Prolift System constitutes major invasive surgery and cannot be accurately characterized as “*minimally invasive*” as described in Ethicon’s patient brochures.

#### 5. Prolift Surgical Results and Efficacy

POP is a quality of life (QOL) issue. It is rarely, if ever, a life-threatening condition. Therefore, POP surgery “success” needs to be defined as whether or not the POP procedure improves or corrects the symptoms that are bothersome to the patient. A surgeon must counsel the patient and justify the relief of POP symptoms against the pain, recovery time, possibility of complications, and expense of POP surgery. With this baseline understanding, it is imperative to analyze the literally thousands of pages of data that exist describing “success” of surgery. To add confusion to the unsuspecting physician and equally unsuspecting patient, all too often, “success” is reported only in terms of “anatomical” results (whether or not the prolapsed pelvic organ was restored to its native position) and not in terms of “symptomatic” results (whether the patient’s POP symptoms were relieved by the POP procedure). Because of this often confusing and misleading reporting style, it is important to review the data focusing on anatomic results versus symptomatic results, and it is important to realize that these two parameters of reported “success” are, by no means, synonymous. Also, it is generally accepted that POP surgical results are essentially meaningless unless they are a minimum of 12 months following surgery, and even 12-month data is of limited value given that the mesh is permanently implanted in a woman’s pelvic tissue and considering the fact that many mesh-related complications manifest years after surgery. Any reported results less than 12 months in duration from the time of POP surgery must be considered preliminary, must be reported as preliminary and, by no means, can be suggestive of being permanent. Any dogmatic statements correlating or suggesting preliminary results with positive long-term results is purposefully misleading and false.

##### a) *Anatomic Results*

Earlier medical literature tended to show that transvaginal anterior mesh POP repair often was able to restore a more normal anatomy compared to traditional non-mesh POP repairs. However, this was only when the strict anatomical stages criteria established by the 2001 National Institutes of Health (NIH) Workshop on Standardization of Terminology for Researchers in Pelvic Floor Disorders were followed. When utilizing the more clinically relevant and contemporary measures of surgical outcomes, the difference in anatomic success becomes negligible. Also of importance is that the risk of complications is higher in the mesh POP repair groups. This fact highlights the critically important issue of the need to balance the anatomic results with mesh-specific complications. Transvaginal mesh posterior and transvaginal mesh apical POP repair procedures do not provide any superior anatomic results compared to traditional, transvaginal non-mesh POP procedures. Also, very interesting data has emerged that shows that women, following POP procedures, that have “perfect vaginal support” actually have a lower QOL and subjective improvement compared with women with lesser degrees of support. This fact points to the dynamic nature of the vagina and indicates the

necessity of maintaining vaginal mobility and elasticity for normal vaginal and pelvic floor functioning.

***b) Symptomatic Results***

To date, regarding specifically anterior transvaginal mesh POP repairs, there is no conclusive evidence within non-industry supported manuscripts published by reputable, peer-reviewed medical and surgical journals that demonstrates a statistically significant improvement in subjective success, QOL, reoperation rates, and POP symptom relief.

Regarding specifically posterior transvaginal mesh POP repairs, there is also no conclusive evidence within non-industry supported manuscripts published by reputable, peer-reviewed medical and surgical journals, which demonstrates a statistically significant improvement in QOL and POP symptom relief.

Regarding specifically apical transvaginal mesh POP repairs, there is no conclusive evidence within non-industry supported manuscripts published by reputable, peer-reviewed medical and surgical journals, which demonstrates a statistically significant improvement in QOL and POP symptom relief.

**6. Summary of Transvaginal Mesh Repair Results**

There are insufficiencies in most POP manuscripts (underpowered, insufficient QOL evaluation, industry sponsored, variability of reporting, insufficient follow-up, insufficient duration, endpoints that are related to anatomic results rather than safety concerns, etc.). Previous manuscripts indicated the “anatomic” success of the isolated anterior compartment with mesh and suggested it to be superior to that of traditional non-mesh repairs. However, when utilizing the more clinically relevant and contemporary measures of surgical outcomes, the difference in anatomic success becomes negligible. The success of transvaginal mesh for both apical and posterior POP repair is equivocal compared to traditional non-mesh repairs. Also, what is highly underreported in the data is that even if POP recurrence occurs following surgery, in either the mesh or non-mesh POP repair patients, the POP recurrence is usually low stage, minimally symptomatic, and usually does not require surgical intervention. Ultimately, however, what matters most to the patient, in contrast to anatomic results, is the relief of the POP symptoms that were bothering the woman in the first place. In this very important issue, there is no data demonstrating that transvaginal mesh POP surgery, in any compartment, has been shown to be superior in symptom relief and QOL to that of traditional, non-mesh repairs.

Also, as mentioned above, data demonstrates that women who have “perfect vaginal support” following POP procedures actually have a lower QOL compared with women with lesser degrees of support. This fact points to the dynamic nature of the vagina and indicates the necessity of maintaining vaginal mobility and elasticity in order for normal vaginal and pelvic floor functioning. Therefore, any procedure that impairs or inhibits the vagina or the pelvic floor’s normal dynamic, mobile and elastic function can greatly impact the normal function.

As discussed earlier in this report, one of the most common arguments used to justify vaginal mesh use over the traditional, non-mesh POP repairs was the previously reported 30-40% failure rates of the traditional repairs. However, currently, within contemporary POP studies,

which utilize up-to-date prolapse definitions, the accepted failure rate of traditional, non-mesh POP repairs is less than 15% and closer to 12%. Therefore, for the benefit of mesh repairs to outweigh the risks, it would seem imperative for the mesh repairs to provide a clear benefit regarding recurrence rates. In 2006, initial Prolift advertising claimed a “less than 5% failure rate” at only three months post-op. However, in Ethicon internal documents it was reported that *“Prof Jacquetin’s data has not proved as positive as hoped – showing approx 80% success rate – The data will be initially presented at IUGA in September. Note that this data is a retrospective study of over 100 patients using TVM technique, not necessarily used with Prolift. This less than 90% success rate forces us to differentiate Prolift from the TVM technique moving forward.”*<sup>55</sup> Because of the disappointing results from the French TVM Study by Jacquetin, et al., Ethicon chose not to inform doctors and patients of those longer-term results and, instead, chose to use extremely short-term results. At the same time, Ethicon knew that the French results showed an 18.4% failure rate at 12 months after surgery. Despite knowing these results, Ethicon used only the purported positive information from the TVM study in their marketing, while choosing to withhold negative data.

## VII. COMPLICATIONS OF PROLIFT REPAIR SYSTEM – SAFETY

### A. Introduction

There is an abundant amount of readily available medical literature with detailed descriptions of the increased number of mesh procedure complications compared to the non-mesh POP procedures. It should be noted that even though the documented complication rate is high with Prolift POP systems, the true incidence is not known due to multiple factors including the critical reality that complications are vastly underreported, with some articles, including one by the former Commissioner of the FDA, estimating that complications are underreported at a rate of 100 to 1.<sup>56</sup> Some mesh-specific complications are devastating to the patient, her sexual partner, and to the overall medical financial burden. Furthermore, some complications are permanent, resulting in lifelong harm and disability to the patient and her partner.

Several factors come into play regarding the increased complication rate with the Prolift POP repair systems. The blind insertion of the trocars into and through deep pelvic structures such as the obturator foramen, ischiorectal fossa, ileococcygeus muscle and the sacrospinous ligament exposes the patient to an increased risk of injury to the rectum, bladder, inferior gluteal blood vessels, pudendal nerve, pudendal artery and vein, and the sciatic nerve. Also, the very presence of large quantities of synthetic, nonabsorbable mesh placed via a transvaginal incision increases the risk of various complications.

Furthermore, the surgeons’ role in performing POP surgery is complicated and does play a role. However, even highly-qualified, high-volume, top-tiered Prolift surgeons report high complication rates relative to both traditional, non-mesh POP as well as mesh repairs using Prolift. The fact that Ethicon specifically targeted “second tier” surgeons to whom they would aggressively market the Prolift only added to the complexities of marketing this “revolutionary”

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<sup>55</sup> ETH.MESH.00741137

<sup>56</sup> Kessler, D: Introducing a New Approach to Reporting Medication and Device Adverse Effects and Product Problems: JAMA, June 2, 1993 – Volume 269, No 21

surgical device and technique to a surgeon population that in many cases, had no idea how to treat the complications that would ensue and that were not warned about by Ethicon.

There is some confusion and misleading documentation discussing whether or not a given mesh-related complication is defined as “rare” or not. There is no single, widely accepted definition for “rare”. In the United States, however, the *Rare Disease Act* of 2002 defines a rare disease strictly according to its prevalence within the community, specifically “*any disease or condition that affects... about 1 in 1,500 people.*” In Japan, the legal definition of a rare disease is one that affects about 1 in 2,500 people. The European Commission on Public Health has defined a rare disease as a condition that occurs in a low prevalence, which they defined as less than 1 in 2,000 people affected. The definitions used in the medical literature and by national health plans are similarly divided, with definitions ranging from 1/1,000 to 1/200,000. Ethicon’s own internal documents define “rare” as 1/100,000.<sup>57</sup> *Based upon these criteria, many, if not most of the mesh-related complications do not fit the definition of “rare”.*<sup>58,59</sup>

## **B. Impaired Vaginal Healing**

At the onset of transvaginal synthetic mesh use for POP, there was confusion in the literature and at scientific meetings as physicians and patients encountered a new set of previously undescribed, mesh-related vaginal complications. Because of this confusion, many early documents underreported or did not report certain complications at all. This may account for vastly differing complication rate results in the literature and the underreporting of complication rates in many reports. Therefore, as a result of the emergence of mesh-specific complications and for clarification and reporting purposes, medical literature has generally adopted descriptive nomenclature (mesh granulation, mesh extrusion, mesh erosion) pertaining to poor mesh healing in the vagina.

Mesh “*granulation*” or “*wound granulation*,” indicates poor vaginal wall healing and possible mesh infection. Symptoms of wound granulation may include foul smelling vaginal discharge, bloody vaginal discharge, pelvic discomfort, pelvic pain, vaginal wound infection and dyspareunia.

It is generally accepted that mesh “erosion,” “*extrusion*” and mesh “exposure” indicates that the inflammation created by the synthetic mesh has impaired vaginal tissue to such a degree so as to cause the mesh to actually be exposed through the vaginal wall. Symptoms may include foul smelling vaginal discharge, bloody vaginal discharge, pelvic discomfort, pelvic pain, vaginal wound infection and dyspareunia. In some patients, the synthetic mesh has worn through the wall of the urethra (the tube urine passes through from the bladder), or the wall of the bladder or the rectal or intestinal wall. This complication can be possibly life threatening. Additional symptoms include foul smelling vaginal discharge, bloody vaginal discharge, pelvic discomfort,

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<sup>57</sup> ETH.MESH.003088817

<sup>58</sup> Gauld depo 4/26/12 197:23-200:15

<sup>59</sup> Hinoul Deposition 4-5-12, p70-72.



pelvic pain, pain with urination, vaginal wound infection, dyspareunia, bowel function abnormalities, bloody bowel movements, bladder infection, fever, and sepsis.<sup>60</sup>

It is probable that wound granulation, vaginal extrusion, and bladder/urethral erosion represent a spectrum of the same problem, with the only difference being the degree to which the impaired healing between the mesh and vagina/bladder has been allowed to proceed. To place each of the mesh “epithelial” complications into separate categories is misleading and minimizes their total number.<sup>61</sup> That said, wound granulation is a relatively common complication and has been reported in ~2-12% of patients. The management of this problem can be minor with most patients being treated with conservative measures and reassurance. Vaginal mesh extrusion has been reported to occur in 10-33% of patients. If this rate were truly accurate, this would represent an estimated 3,750 to 7,500 women per year in the United States in 2010 alone. Highly skilled, high-volume POP surgeons reported a vaginal extrusion rate of up to 12%. Therefore, the argument that vaginal extrusion is limited or solely due to surgeon inexperience does not hold true when examining the available literature.

Treatment ranges from observation alone in mild cases to estrogen therapy and antibiotics. If conservative measures fail or the size of the mesh extrusion is too great or the patient’s symptoms are too significant, then a surgical procedure to remove the exposed vaginal mesh is necessary. It is estimated that 75% of patients that present with vaginal mesh extrusion will ultimately require some form of surgical repair and excision of the exposed mesh.<sup>62</sup> Unfortunately, simple surgical removal is not always successful and creates even further risk of injury to the patient including, but certainly not limited to, vesicovaginal fistulas (a hole between the bladder, rectum and vagina). This problem requires extensive, complicated, and advanced surgery to repair, prolonged recovery for the patient and significant added medical expense.<sup>63,64,65,66</sup>

Ethicon’s Device Design Safety Assessment states that the probability of hazard for postoperative tissue erosion is occasional (1 in 10,000 maximum). However, by 2006, there was abundant evidence in the literature describing mesh complications with erosions at a significantly

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<sup>60</sup> Haylen B, Freeman R, Swift S et al: An International Urogynecological Association (IUGA) / International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) & grafts in female pelvic floor surgery. *Int Urogynecol J* (2011) 22:3–15.

<sup>61</sup> Haylen B, Freeman R, Swift S et al: An International Urogynecological Association (IUGA) / International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) & grafts in female pelvic floor surgery. *Int Urogynecol J* (2011) 22:3–15.

<sup>62</sup> Abbott S, Unger CA, Evans JM, Karram M et al. Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study. *Am J Obstet Gynecol* 2014;210:163.e1-8.

<sup>63</sup> Boyles SH, McCrery R., Dyspareunia and mesh erosion after mesh placement with a kit procedure. *Obstet Gynecol*. 2008 Apr;111(4):969-75

<sup>64</sup> Deffieux X, De Tayrac R, Huel C, et al. Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study. *Int Urogynecol J Pelvic Floor Dysfunct*. 2007 Jan;18(1):73-9.

<sup>65</sup> Firoozi F, Goldman H. Transvaginal excision of mesh erosion involving the bladder after mesh placement using a prolapse kit - a novel technique. *Urology*. 2010 Jan;75(1):203-6.

<sup>66</sup> Abed H, Rahn D, Lowenstein L, et al. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. *Int Urogynecol J*. 2011 Jul;22(7):789-98.

higher rate.<sup>67,68,69,70,71,72,73,74</sup> Ethicon internal documents and studies indicate that postoperative vaginal erosion/extrusion/exposure occurred in 13.7% of cases (U.S. TVM arm = 14.1%; and French TVM arm = 10%). Over 50% of these exposures required surgical treatment.<sup>75,76,77,78,79,80</sup>

In the Prolift patient brochure, FDA requested that Ethicon “include a statement under the ‘What are the risks?’ section (p.13) which reflects that one of the most common adverse event[s] is mesh extrusion [exposure] and this complication usually requires the removal of the mesh and may interfere with sexual function”.<sup>81</sup> Instead of following the FDA’s request, Ethicon changed this section to state, “There is also a risk of the mesh material becoming exposed in the vaginal canal.” They also ignored the FDA’s request when they stated, “This information is based on our Medical expert’s input on the standard means of treating mesh exposures, many of which resolve spontaneously or with medication.” Of course, the medical literature at the time (May 2008) indicated that virtually no cases of mesh exposure resolve “spontaneously.” A literature search for mesh exposure through May 2008 demonstrates an overall 221 mesh exposures in 2138 patients (10.3%). Of those patients, 130 of 195 (66.7%) required mesh excision after exposure.<sup>82,83,84,85,86,87,88,89</sup> Mesh erosions were such a frequent and severe reported

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<sup>67</sup> Bader G, Fauconnier A, Roger N et al: Cystocele repair by vaginal approach with a tension-free transversal polypropylene mesh. Technique and results. Gynecologie Obstetrique & Fertilité 32 (2004) 280-284.

<sup>68</sup> Milani R, Salvatore S, Soligo M, et al. Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh. BJOG. 2005 Jan;112(1):107-11.

<sup>69</sup> De Tayrac R, Gervaise A, Chauveaud A et al: Combined genital prolapse repair reinforced with a polypropylene mesh and tension-free vaginal tape in women with genital prolapse and stress urinary incontinence: a retrospective case-control study with short-term follow-up. Acta Obstet Gynecol Scand. 2004 Oct;83(10):950-4.

<sup>70</sup> De Tayrac R, Gervaise A, Chauveaud A et al: Tension-free polypropylene mesh for vaginal repair of anterior vaginal wall prolapse. J Reprod Med. 2005 Feb;50(2):75-80.

<sup>71</sup> Jacquetin B, Cosson M, Lucente V et al: Prospective clinical assessment of the transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse-one year results of 175 patients. (Abstract #291: Presentation International Continence Society 2006).

<sup>72</sup> Benhaim Y, de Tayrac R, Deffieux X, Gervaise A et al: Treatment of genital prolapse with a polypropylene mesh inserted via the vaginal route. Anatomic and functional outcome in women aged less than 50 years. J Gynecol Obstet Biol Reprod (Paris). 2006 May;35(3):219-26.

<sup>73</sup> Cosson M, Debodinance P, Boukerrou M et al: Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J (2003) 14:169-178.

<sup>74</sup> Debodinance P, Engrand J. Development of better tolerated prosthetic materials: applications in gynecological surgery. J Gynecol Obstet Biol Reprod (Paris). 2002 Oct;31(6):527-40.

<sup>75</sup> ETH.MESH.00081035

<sup>76</sup> ETH.MESH.00081083

<sup>77</sup> ETH.MESH.00080954

<sup>78</sup> ETH.MESH.00081006

<sup>79</sup> ETH-01121 – 01122

<sup>80</sup> ETH.MESH.00081000 – 00081001

<sup>81</sup> ETH-01322

<sup>82</sup> Milani R, Salvatore S, Soligo M, et al. Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh. BJOG. 2005 Jan;112(1):107-11.

<sup>83</sup> De Tayrac R, Gervaise A, Chauveaud A et al: Tension-free polypropylene mesh for vaginal repair of anterior vaginal wall prolapse. J Reprod Med. 2005 Feb;50(2):75-80.

<sup>84</sup> De Tayrac R, Deffieux X, Gervaise A et al: Long term anatomical and functional assessment of trans vaginal cystocele repair using polypropylene mesh. Int Urogynecol J Pelvic Floor Dysfunct. 2006 Sep;17(5):483-8.

<sup>85</sup> Collinet P, Belot F, Debodinance P et al. Transvaginal mesh technique for pelvic organ prolapse repair: mesh exposure management and risk factors. Int Urogynecol J (2006) 17:315-320.

complication that Ethicon's internal documents are filled with internal studies and emails, presentations, design change considerations, retention of external consultants and meetings at high levels within the company in attempts to address this serious adverse complication in women's pelvic tissues.<sup>90</sup>

### C. Continuous Organ Injury

Ethicon's Device Design Safety Assessment (DDSA) also states that the expected risk of vital organ perforation with the Prolift procedure is "rare" (1 in 100,000 maximum). However, injury to adjacent pelvic organs is *not* rare and has been reported to occur in as many as 3-6.6% of pelvic mesh patients implanted with the Prolift System. This is due to the fact that the female pelvis is tightly packed with multiple anatomic structures in very close spatial proximity. This spatial arrangement demands the highest surgical skill even without multiple blind passes into the deep pelvic spaces with trocars contained in the Prolift System. Even the surgeons involved in the TVM study (4 years, 600 patients) had 1.9 % bladder and other organ perforations. Ethicon's website listed 1.9% bladder perforations, 1.2% rectal perforations and urethral damage 0.5% for a combined total of 3.6% perforations. Despite these known rates of complications of organ perforation by Ethicon, its DDSA was apparently never updated with accurate figures, and more importantly, this high rate of complications was not properly communicated to surgeons or patients.

All Prolift trocars are passed blindly and, even in highly trained surgical hands, serious injury can result to the bladder, ureter, pelvic nerves, and potentially life-threatening injury to major pelvic blood vessels can occur. This issue takes on even far greater importance when considering the varying level of skill and experience many surgeons have with the Prolift System. Additionally, if blood vessels are damaged, it may be difficult, if not impossible, to recognize and treat such injuries as they are likely to be deep within the woman's pelvis.<sup>91,92,93,94</sup>

### D. Bladder Injury/Perforation

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<sup>86</sup> Deffieux X, De Tayrac R, Huel C, et al. Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study. *Int Urogynecol J Pelvic Floor Dysfunct.* 2007 Jan;18(1):73-9.

<sup>87</sup> Fatton R, Amblard P, Debodinance P. Transvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift technique)--a case series multicentric study. *Int Urogynecol J Pelvic Floor Dysfunct.* 2007 Jul;18(7):743-52.

<sup>88</sup> Altman D, Tapio V et al. Short-term outcome after transvaginal mesh repair of POP. *Int Urogynecol J* (2008) 19:787-793.

<sup>89</sup> Abdel Fattah I, Ramsey I. Retrospective multicentre study of the new minimally invasive mesh repair devices for POP. *BJOG.* 2008 Jan;115(1):22-30.

<sup>90</sup> ETH.MESH.07192929, ETH.MESH.02270724, ETH.MESH.00584846, ETH.MESH.01220730, ETH.MESH.02157879, ETH.MESH.00006636, ETH.MESH.07200382

<sup>91</sup> ETH.MESH.PM.000019

<sup>92</sup> Chen C, Gustilo-Ashby AM et al. Anatomic relationships of the tension free vaginal mesh trocars. *Am J Obstet Gynecol.* 2007 Dec;197(6):666.e1-6.

<sup>93</sup> Haylen B, Freeman R, Swift S et al: An International Urogynecological Association (IUGA) / International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) & grafts in female pelvic floor surgery. *Int Urogynecol J* (2011) 22:3-15.

<sup>94</sup> Vierhout M, Withagen M, Futterer J: Rectal obstruction after a vaginal posterior compartment polypropylene mesh fixed to the sacrospinous ligaments. *Int Urogynecol J* (2011) 22:1035-1037.

Bladder perforation by the Prolift trocars tends to be one of the more common injuries with a reported incidence of up to 6%. Due to the obvious frequency of bladder perforation, Ethicon should have required from the outset that cystoscopy be performed at the time of the Prolift POP surgery in order to detect and treat a bladder perforation should one exist. An unrecognized bladder perforation undoubtedly leads to a significant number of complications that could otherwise be avoided by cystoscopy.<sup>95,96,97,98</sup>

#### **E. Rectal Injury/Perforation**

The incidence of rectal perforation at the time of Prolift POP procedures is less common than those of bladder perforation with a known reported incidence of 0.4-1.2%. Although rectal perforation is less common, the potential severe consequences of a rectal perforation, especially one that goes unrecognized, can be devastating and life threatening. Also, rectal obstruction and rectal-vaginal fistula following the implantation of the Prolift System have been reported. These potentially devastating complications require immediate and skilled intervention to prevent severe complications including death. Following both the Prolift Posterior and the Prolift Total POP procedure, a rectal exam should be performed to check for inadvertent rectal cuts or perforations and to ensure that there has not been any narrowing of the rectum.<sup>99,100,101,102</sup>

#### **F. Vascular Injury**

Several sets of major blood vessels (the pudendal, the obturator and the inferior gluteal) are at significantly increased risk for intraoperative injury compared to traditional, non-mesh, and non-trocar POP procedures. These large, major blood vessels are at increased risk due to their close anatomic proximity during the several blind Prolift trocar passages through the pelvic tissue. The internal pudendal artery and vein are at increased risk by the trocar of the Prolift Posterior and Prolift Total Pelvic Floor Repair System because these procedures pass the trocars through the sacrospinous ligament. Any blood vessel injury represents a significant and potentially life threatening condition for the patient. Ethicon's documents indicate awareness of this increased risk at least as early as 2005.<sup>103,104,105</sup>

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<sup>95</sup> ETH-01761

<sup>96</sup> Henderson Deposition 10-5, p457

<sup>97</sup> Haylen B, Freeman R, Swift S et al: An International Urogynecological Association (IUGA) / International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) & grafts in female pelvic floor surgery. *Int Urogynecol J* (2011) 22:3-15.

<sup>98</sup> Firoozi F, Goldman H. Transvaginal excision of mesh erosion involving the bladder after mesh placement using a prolapse kit - a novel technique. *Urology*. 2010 Jan;75(1):203-6.

<sup>99</sup> ETH.MESH.PM.000019

<sup>100</sup> ETH.MESH.00067362

<sup>101</sup> Haylen B, Freeman R, Swift S et al: An International Urogynecological Association (IUGA) / International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) & grafts in female pelvic floor surgery. *Int Urogynecol J* (2011) 22:3-15

<sup>102</sup> Vierhout M, Withagen M, Futterer J: Rectal obstruction after a vaginal posterior compartment polypropylene mesh fixed to the sacrospinous ligaments. *Int Urogynecol J* (2011) 22:1035-1037.

<sup>103</sup> ETH-48769

<sup>104</sup> Gangam N, Kanee A: Retroperitoneal hemorrhage after a vaginal mesh prolapse procedure. *Obstet Gynecol*. 2007 Aug;110(2 Pt 2):463-4.



## G. Nerve Injury

Pelvic nerve injury is a critically important and under-diagnosed condition following Prolift POP repair. The nerves most specifically at risk are the pudendal nerve and the levator ani nerve. These nerves have critical bladder and pelvic floor functions. However, the pelvic anatomy and specifically the neuroanatomy can vary significantly between patients. Any direct nerve injury during the blind Prolift trocar passage or nerve entrapment by one or more of the Prolift mesh arms can greatly impact the patients' bladder function leading to urinary retention, bladder spasms, urinary leakage and pelvic floor pain syndromes including sexual function dysfunction. Multiple factors increase the likelihood of nerve injury including the multiple blind trocar passes; the close proximity of important nerves to these trocars; and, insufficiently trained or novice surgeons. Specifically, these factors play a role in levator ani nerve injury.<sup>106,107,108,109,110,111,112, 113, 114, 115</sup>

The pudendal nerve is susceptible to trocar injury, entrapment, or inflammation secondary to mesh contraction. The pudendal nerve has both sensory and motor function; therefore, when damaged or irritated the pudendal nerve affects both the patient's sensation and the function of key motor/muscle groups. The pudendal nerve crosses the sacrospinous ligament in various locations thereby making it especially susceptible to injury during the blind passage of the trocars. Injury to the pudendal nerve can lead to a painful pelvis syndrome called Pudendal Nerve Neuralgia, which results in a debilitating chronic pelvic pain syndrome.

Despite the knowledge that the Prolift System could damage the pudendal nerve, Ethicon elected not to include a statement regarding the risk of Prolift POP surgery causing "pain with

<sup>105</sup> Ignjatovic I, Stosic D: Retrovesical haematoma after anterior Prolift procedure for cystocele correction. *Int Urogynecol J Pelvic Floor Dysfunct.* 2007 Dec;18(12):1495-7. Epub 2007 Jun 29.

<sup>106</sup> ETH.MESH.PM.000019

<sup>107</sup> Haylen B, Freeman R, Swift S et al: An International Urogynecological Association (IUGA) / International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) & grafts in female pelvic floor surgery. *Int Urogynecol J* (2011) 22:3–15.

<sup>108</sup> Takeyama M, Koyama M, Murakami G et al: Nerve preservation in the tension free vaginal mesh procedures for pelvic organ prolapse - a cadaveric study. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008 Apr;19(4):559-66. Epub 2007 Oct 10.

<sup>109</sup> Altman D, Zhang A, Falconer C: Innervation of the rectovaginal wall in patients with rectocele compared to healthy controls. *Neurourology and Urodynamics* 25:776-781.

<sup>110</sup> Haylen B, Freeman R, Swift S et al: An International Urogynecological Association (IUGA) / International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) & grafts in female pelvic floor surgery. *Int Urogynecol J* (2011) 22:3–15.

<sup>111</sup> Winnard KP, Dmitrieva N, Berkley KJ. Cross-organ interactions between reproductive, gastrointestinal, and urinary tracts: modulation by estrous stage and involvement of the hypogastric nerve. *Am J Physiol Regul Integr Comp Physiol* 291: R1592–R1601, 2006.

<sup>112</sup> Ustinova EE, Fraser MO, Pezzone MA. Colonic irritation in the rat sensitizes urinary bladder afferents to mechanical and chemical stimuli: an afferent origin of pelvic organ cross-sensitization. *Am J Physiol Renal Physiol* 290: F1478–F1487, 2006.

<sup>113</sup> Ustinova et al: Sensitization of pelvic nerve afferents and mast cell infiltration in the urinary bladder following chronic colonic irritation is mediated by neuropeptides. *Am J Physiol Renal Physiol* 292: F123–F130, 2007.

<sup>114</sup> Ruddick CN, Chen MC, Mongiu AK, Klumpp DJ. Organ cross talk modulates pelvic pain. *Am J Physiol Regul Integr Comp Physiol* 2007;293: R1191–8.

<sup>115</sup> Pezzone MA, Liang R, Fraser MO. A model of neural cross-talk and irritation in the pelvis: implications for the overlap of chronic pelvic pain disorders. *Gastroenterology* 128: 1953–1964, 2005.

intercourse and pelvic pain”.<sup>116</sup> Also, at the Ethicon Expert Meeting regarding Meshes for Pelvic Floor Repair in June 2006, data was clearly presented which detailed mesh-related nerve damage, the risk of nerve damage, and the consequences of the damage.<sup>117</sup>

## H. Urinary Tract Dysfunction and Incontinence

Urination difficulties following Prolift POP procedures include prolonged urinary retention (the inability to void), urinary urgency, urge incontinence, urinary frequency, and new onset stress urinary incontinence (leakage with activity). The incidence of these complications has been reported to occur in as many as 1 in 4 (25%) of women following Prolift POP repair.<sup>118,119,120</sup> Ethicon did not identify voiding dysfunction as a risk in the original Prolift IFU.<sup>121,122,123</sup> However, as early as October 2005, Ethicon’s documents show severe and prolonged urinary retention in patients after Prolift surgery. Dr. David Robinson, newly hired into the position of Medical Director at Ethicon, discussed the need to add the risk of postoperative urinary retention to the Prolift IFU. Despite several meetings to consider this, the Prolift IFU was not revised to include this important information until October 2009. As a result, neither physicians nor patients were adequately informed about this potential risk.

Urinary urgency, frequency, and urge incontinence can have a significant negative impact on a woman’s quality of life, and the conditions can lead to impaired sleep, impaired sexual function, decreased socialization and depression. Even after the revised Prolift IFU was finally made available in October 2009, Ethicon’s statement regarding voiding dysfunction was inadequate in that it was vague and read as if the same risk applied to all pelvic floor repair procedures. This, however, is not the case as the severe and prolonged urinary retention after the Prolift procedure is likely related to the extensive dissection around the sacrospinous ligaments on both the right and left sides of the patient. This extensive dissection, along with the attendant scarring, disrupts the pelvic splanchnic nerves, which normally provide parasympathetic nervous input that controls the bladder’s detrusor muscle, resulting in normal detrusor contractions and bladder emptying. Accordingly, the implication in Ethicon’s revised IFU for Prolift that the risks

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<sup>116</sup> ETH-80318

<sup>117</sup> ETH-80645-80651

<sup>118</sup> Kasturi S, Diaz S, McDermott C et al: De novo stress urinary incontinence after negative prolapse reduction stress testing for total vaginal mesh procedures: incidence and risk factors. *Am J Obstet Gynecol.* 2011 Nov;205(5):487.e1-4. Epub 2011 Jul 20.

<sup>119</sup> Roy S, Mohandas A, Coyne K et al: Assessment of the psychometric properties of the short-form prolapse/urinary incontinence sexual questionnaire (PISQ-12) following surgical placement of Prolift+M: A transvaginal partially absorbable mesh system for the treatment of pelvic organ prolapse. *J Sec Med* 2012;9:1190-1199

<sup>120</sup> Aungst MJ, Friedman EB. De novo stress incontinence and pelvic symptoms after transvaginal mesh repair. *Am J Obstet Gynecol.* 2009 Jul;201(1):73.e1-7

<sup>121</sup> ETH-80249 (email from David Robinson to Giselle Bonett, description of 4 cases of total Prolift: “In folks with normal preop voiding function, who then post Prolift can can’t void [due to bladder atony].... Some have resolved spontaneously but have taken as long as a year to do so.... [t]he cases seem to have no common thread or any difficulty with the surgery itself. But if this starts getting reported, it is going to scare the daylights out of docs ....”)

<sup>122</sup> ETH-01762 (“Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.”)

<sup>123</sup> ETH-80297: Jan. 26-27, 2006 email chain about revising the Prolift IFU: “Dissection for Prolift and any similar procedure has the potential to impair normal voiding for variable length of time”)

of urinary problems with the Prolift are comparable to that of all pelvic floor repair procedures is misleading at best.

## I. Mesh Contraction

Polypropylene surgical mesh is known to contract and shrink when placed in the body.<sup>124,125,126,127,128,129,130,131,132,133,134,135,136,137,138,139,140</sup> Vaginal mesh contraction can result in vaginal fibrosis, infection, chronic vaginal pain, chronic pelvic pain, vaginal shortening, vaginal narrowing, vaginal extrusion, adjacent organ erosion, dyspareunia, recurrence and the need for surgical intervention. The reported incidence (which likely underestimates the degree of the problem) ranges from 11 to 20%. However, because of multiple varying factors such as reporting variations, under-reporting, short-term reporting, patient and physician ignorance, and delayed presentation, it is impossible to know the true incidence and severity of vaginal mesh contraction.<sup>141,142,143,144,145,146,147,148,149,150,151,152,153,154,155,156,157,158,159,160</sup> Feiner and Maher

<sup>124</sup> ETH-80645 – 80651

<sup>125</sup> Robinson Deposition 3-13, p206

<sup>126</sup> Kirkemo Deposition, p153-154

<sup>127</sup> Walji Deposition p465

<sup>128</sup> Hinoul Deposition 4-5, p132-133

<sup>129</sup> Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. *Hernia* (1997) 1:15-21.

<sup>130</sup> Bouikerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. *European J. Obstet & Gynecol and Repro Bio* 134: (2007) 262-267.

<sup>131</sup> Boukerrou M, Rubod C, Dedet B et al: Tissue resistance of free tension procedure: What about healing? *Int Urogynecol J* (2008) 19:397-400. Published online Sept 2007.

<sup>132</sup> Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. *Eur J Surg.* 1999 Jul;165(7):665-73.

<sup>133</sup> Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. *European Journal of Surgery* Volume 164, Issue 12, pages 965–969, December 1998.

<sup>134</sup> Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. *Biomaterials.* 1998 Dec;19(24):2235-46.

<sup>135</sup> Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. [ABSTRACT] *Chirurg* 2000;71:43-51.

<sup>136</sup> Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. *Expert Rev Med Devices.* 2005 Jan;2(1):103-17.

<sup>137</sup> Krambeck A, Dora C, Elliott D. Time-dependent variations in inflammation and scar formation of six different pubovaginal sling materials in the rabbit model. *Urology.* 2006 May;67(5):1105-10.

<sup>138</sup> Krause H, Galloway S, Khoo S et al: Biocompatible properties of surgical mesh using an animal model. *Aust N Z J Obstet Gynaecol.* 2006 Feb;46(1):42-5.

<sup>139</sup> Hilger W, Walter A, Zobitz M et al: Histological and biomechanical evaluation of implanted graft materials in a rabbit vaginal and abdominal model. *Am J Obstet Gynecol* 2006; 195:1826-31.

<sup>140</sup> Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. *American Journal of Surgery* Vol 193, Issue 4, April 2007, p538-542.

<sup>141</sup> ETH.MESH.00067360

<sup>142</sup> ETH-80645 – 80651

<sup>143</sup> Aungst MJ, Friedman EB. De novo stress incontinence and pelvic symptoms after transvaginal mesh repair. *Am J Obstet Gynecol.* 2009 Jul;201(1):73.e1-7.

<sup>144</sup> Caquant F, Collinet P, Deobodianance P, et al. Safety of transvaginal mesh procedure: retrospective study of 684 patients. *J Obstet Gynaecol Res.* 2008 Aug;34(4):449-56.

<sup>145</sup> Argirovic RB, Gudovic AM et al, Transvaginal repair of genital prolapse with polypropylene mesh using tension-free technique. *Eur J Obstet Gynecol Reprod Biol.* 2010 Nov;153(1):104-7.

evaluated 17 women with vaginal mesh contraction to demonstrate that the mesh caused the condition. The patients' presenting complaints included severe vaginal pain, dyspareunia, and focal tenderness over contracted portions of mesh on vaginal examination, mesh erosion, vaginal tightness, and vaginal shortening. The patients underwent surgical intervention with mobilization of mesh from underlying tissue, division of fixation arms of the central graft, and excision of contracted mesh. Fifteen of 17 (88%) patients reported a 'substantial reduction in vaginal pain following explantation, while 11 of 17 (64%) reported 'substantial' reduction in dyspareunia. However, despite Feiner's relative success with mesh explanation, the adverse effects of transvaginal mesh contraction caused permanent life-altering sequelae in 22-46% of patients in this study.

More recently, Letouzey et al. reviewed the long-term changes in pelvic mesh volumes over time using three-dimensional translabial ultrasonography and found mean contraction of 30%, 65%, 85% at follow-up durations of 3, 6, and 8 years, respectively. This study demonstrates that the pathological process that causes mesh shrinkage is progressive and there is a linear evolution of the contraction rate with time.

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<sup>146</sup> Clave A, Yahi H, Hammou J, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 patients. *Int Urogynecol J*. 2010 Mar;21(3):261-70.

<sup>147</sup> Blandon RE, Gebhart JB et al. Complications from vaginally placed mesh in pelvic reconstructive surgery. *Int Urogynecol J Pelvic Floor Dysfunct*. 2009 Feb 10.

<sup>148</sup> Collinet P, Belot F, Debodinance P et al. Transvaginal mesh technique for pelvic organ prolapse repair: mesh exposure management and risk factors. *Int Urogynecol J* (2006) 17:315-320.

<sup>149</sup> Abed H, Rahn D, Lowenstein L, et al. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. *Int Urogynecol J*. 2011 Jul;22(7):789-98.

<sup>150</sup> Deffieux X, De Tayrac R, Huel C, et al. Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study. *Int Urogynecol J Pelvic Floor Dysfunct*. 2007 Jan;18(1):73-9.

<sup>151</sup> Feiner B, Maher C. Vaginal mesh contraction: definition, clinical presentation, and management. *Obstet Gynecol*. 2010 Feb;115(2 Pt 1):325-30.

<sup>152</sup> Foon R, Toozs-Hobson P, Latthe P. Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008 Dec;19(12):1697-706.

<sup>153</sup> Krause H, Bennett M, Forwood M. Biomechanical properties of raw meshes used in pelvic floor reconstruction. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008 Dec;19(12):1677-81.

<sup>154</sup> Dietz H, Vancaillie P, Svehla M. Mechanical properties of urogynecologic implant materials. *Int Urogynecol J Pelvic Floor Dysfunct*. 2003 Oct;14(4):239-43.

<sup>155</sup> Debodinance P, Engrand J. Development of better tolerated prosthetic materials: applications in gynecological surgery. *J Gynecol Obstet Biol Reprod (Paris)*. 2002 Oct;31(6):527-40.

<sup>156</sup> Martan A, Svabik K. et al. Incidence and prevalence of complications after urogynecological and reconstructive pelvic floor surgery. *Ceska Gynecol*. 2007 Dec;72(6):410-5.

<sup>157</sup> Jia X, Glazener C, Mowatt G, et al. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systemic review and meta-analysis. *BJOG* 2008 Oct;115(11):1350-61.

<sup>158</sup> Falagas M, Velakoulis S, Iavazzo C, et al. Mesh-related infections after pelvic organ prolapse repair surgery. *Eur J Obstet Gynecol Reprod Biol*. 2007 Oct;134(2):147-56.

<sup>159</sup> Firoozi F, Goldman H. Transvaginal excision of mesh erosion involving the bladder after mesh placement using a prolapse kit - a novel technique. *Urology*. 2010 Jan;75(1):203-6.

<sup>160</sup> Diwadkar G, Barber M, Feiner B, et al. Complications and reoperation rates after apical vaginal prolapse surgical repair: a systematic review. *Obstet Gynecol*. 2009 Feb;113(2 Pt 1):367-73.



At the IUGA Conference in 2009, the inventor of the TVM technique used in the Prolift system, Prof Jacquetin, presented data indicating that painful mesh contraction occurred at a rate of 19.6%.<sup>161</sup>

A consistently worrisome statistic is that many of the complications related to mesh contraction such as pelvic pain and dyspareunia are delayed in onset. Given the currently reported complication rates, there are a large number of women around the world who have yet to develop problems but given enough time will. In other words, we may be seeing just the tip of the iceberg.<sup>162</sup> Ethicon's own internal documents indicate a substantial risk of mesh shrinkage of at least 20% at one year with resultant mesh retraction and vaginal pain.<sup>163,164,165,166,167</sup> However, neither the original Prolift IFU nor the Surgical Guide adequately warned of the risk of mesh contraction. Ethicon also knew from a 2005 article by Cobb et al that *"All available meshes, regardless of their composition, experience a 20-50% reduction in their initial size. Factors of the mesh itself and the surrounding tissue inflammatory response contribute to this phenomenon."*<sup>168,169</sup>

In addition, the Prolift IFU did not report the negative consequences of mesh contraction, which were known by Ethicon, such as *"vaginal anatomic distortion,"* pelvic pain, vaginal pain, *"negative impact on sexual function,"* *"difficult treatment"* and *"stiffness of the vagina that further impacts sexual function in a negative manner."* Instead of properly warning of these potential problems, the Prolift IFU misleadingly claimed was that *"the mesh remains soft and pliable, and normal wound healing is not noticeably impaired."*<sup>170</sup> The Prolift patient information brochure misleadingly stated: *"[Prolift] allows for the restoration of sexual function by restoring vaginal anatomy."*<sup>171</sup> Given the known high rates and amounts of shrinkage, such statements were false and misleading.<sup>172</sup> Physicians were thus misled into believing that contraction was a positive process for the patient, rather than a negative, and in some cases devastating process.

## J. Foreign Body Reaction

An abundant amount of medical literature and basic science data over the past 40 years indicates the strong and direct relationship between postoperative complications and mesh design.<sup>173,174,175,176,177,178,179,180,181,182,183,184,185</sup> Reducing mesh-related complications demands a

<sup>161</sup> L. Velemir, B. Fatton, B. Jacquetin: Mesh shrinkage: How to asses, how to prevent, how to manage. IUGA Como, Italy June 16-20, 2009

<sup>162</sup> ETH-80645 - 80651

<sup>163</sup> ETH-02326

<sup>164</sup> Robison Deposition 3-13, p260

<sup>165</sup> Kirkemo Deposition p153-154

<sup>166</sup> Walji Deposition p465

<sup>167</sup> Hinoul Deposition 4-5, p132-133

<sup>168</sup> ETH.MESH.01210562

<sup>169</sup> ETH-80645-80651

<sup>170</sup> ETH.MESH.00095913 - 00095918

<sup>171</sup> ETH-00259

<sup>172</sup> ETH-80645 - 80651

<sup>173</sup> ETH-80645 - 80651

<sup>174</sup> Kirkemo Deposition 4-18, p125-131

<sup>175</sup> Robinson Deposition 3-13, p129-130

thorough understanding and knowledge of the chemical, physical and synthetic characteristics of meshes and how they react inside the human body. Based upon vast amounts of general surgery and basic science literature, there is a consensus that synthetic meshes that are lighter weight, larger pore size, monofilament, and that are capable of maintaining their elasticity and structural stability will have better results with fewer complications. Of all the mesh characteristics mesh porosity, mesh pore size and mesh stability under load are the most important. If a mesh product's design does not allow for effective tissue integration and fibrotic bridging occurs, leading to a rigid scar plate, many adverse events can occur such as erosion, nerve entrapment, pain syndromes, dyspareunia, loss of elasticity, mesh contraction, organ dysfunction and the need for reoperation.<sup>186,187,188,189,190,191,192</sup>

White et al. published an article suggesting that inflammatory response may also be explained by the amount of movement of the implant and mechanical stresses that are placed on the mesh. As the movement and mechanical stresses of the pelvic floor differ extensively to that of the abdominal wall, it should have been obvious to Ethicon that the inflammatory response would not only be different, but also more intense in a pelvic floor implant.

In the late 1990's, studies were published by Klinge et al. in which explanted hernia mesh was analyzed from rats, dogs and humans. They discovered that in some patients, a chronic foreign body reaction could still be observed after 15 years. Given that this implant is meant to be placed permanently in a woman's pelvic tissue, to base the safety and efficacy of Prolift on studies that were short-term (6 months or less in duration), while studies were available in the scientific literature showing potential complications up to 15 years, was irresponsible. Generally

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<sup>176</sup> Amid PK. Classification of biomaterials and their related complications in abdominal wall hernia surgery. *Hernia* (1997) 1:15-21.

<sup>177</sup> Bouikerrou M, Boulanger L, Rubod C et al: Study of the biomechanical properties of synthetic implanted in vivo. *European J. Obstet & Gynecol and Repro Bio* 134: (2007) 262-267.

<sup>178</sup> Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. *Eur J Surg.* 1999 Jul;165(7):665-73.

<sup>179</sup> Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. *J. Surgical Research* 103, 208-214 (2002).

<sup>180</sup> Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. *European Journal of Surgery Volume* 164, Issue 12, pages 965-969, December 1998.

<sup>181</sup> Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. *Biomaterials.* 1998 Dec;19(24):2235-46

<sup>182</sup> Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. [ABSTRACT] *Chirugr* 2000;71:43-51.

<sup>183</sup> Krause H, Galloway S, Khoo S et al: Biocompatible properties of surgical mesh using an animal model. *Aust N Z J Obstet Gynaecol.* 2006 Feb;46(1):42-5.

<sup>184</sup> Garcia M, Ruiz V, Godoy A, et al: Differences in polypropylene shrinkage depending on mesh position in an experimental study. *American Journal of Surgery Vol* 193, Issue 4, April 2007, p538-542.

<sup>185</sup> Cappelletti M, Attolini G, Cangioni G, et al. The use of mesh in abdominal wall defects. *Minerva Chir.* 1997 Oct;52(10):1169-76.

<sup>186</sup> ETH.MESH.00869977 - 00870098

<sup>187</sup> ETH.MESH.02589033 - 02589079

<sup>188</sup> ETH-80645 - 80651

<sup>189</sup> Robinson Deposition 3-13, p 120

<sup>190</sup> Hinoul Deposition 4-5, p165-170

<sup>191</sup> Robinson Deposition 3-13, p129-130

<sup>192</sup> Kirkemo Deposition 4-18, p138

speaking, the women who undergo these POP mesh procedures are between 30 and 60 years of age. To have a chronic foreign body reaction that can continue for an unmeasured amount of time in a woman who will have this mesh implanted for decades is unsafe and can potentially lead to life-long debilitating pain and complications. Studies that analyzed the complications that occur years after implantation, such as those performed by Klinge and his colleagues, should have provided Ethicon with a more comprehensive understanding of the true long-term risks and complications to patients, and at the very least, should have prompted Ethicon to conduct long-term controlled studies prior to any marketing of the Prolift System.<sup>193,194,195,196,197,198</sup>

Despite the vast amount of data regarding mesh-related inflammatory response, the original and the revised IFU for Prolift claim that “...*implantation of Gynecare Gynemesh PS mesh elicits a minimum to slight inflammatory reaction, which is transient*”.<sup>199,200</sup> However, Ethicon, according to an internal Ethicon email from Scott Jones dated 11-12-2008, knew this was not true because “*Polypropylene creates an intense inflammatory response that results in rapid and dense incorporation into the surrounding tissues...*”<sup>201</sup> The internal Ethicon documents and depositions are filled with references to the chronic foreign body reaction and inflammatory response by the body to the mesh.

#### K. Degradation

As polypropylene has been used in surgery for over 50 years as a suture material, the mesh in the Prolift System was marketed by Ethicon as inert. However, many published studies and internal Ethicon documents prove otherwise.<sup>202,203,204,205,206,207,208,209,210</sup>

<sup>193</sup> Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul;165(7):665-73.

<sup>194</sup> Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002).

<sup>195</sup> Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998.

<sup>196</sup> Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Biomaterials. 1998 Dec;19(24):2235-46.

<sup>197</sup> Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. [ABSTRACT] Chirugr 2000;71:43-51.

<sup>198</sup> Klosterhalfen B, Junge K, Klinge W. The lightweight and large porous mesh concepts for hernia repair. Expert Rev Med Devices. 2005 Jan;2(1):103-17.

<sup>199</sup> ETH-00005 (Original)

<sup>200</sup> ETH-01764 (Revised)

<sup>201</sup> ETH.MESH.00087294

<sup>202</sup> ETH.MESH.02589066-02589068

<sup>203</sup> ETH-80645-80651

<sup>204</sup> Robinson Deposition 3-14, p 532-533

<sup>205</sup> Kirkemo Deposition 4-18, p137-138

<sup>206</sup> Klinge U, Klosterhalfen B, Muller M et al: Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999 Jul;165(7):665-73.

<sup>207</sup> Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. J. Surgical Research 103, 208-214 (2002).

<sup>208</sup> Klinge U, Klosterhalfen M, Muller A et al: Shrinking of polypropylene mesh in vivo: an experiment study in dogs. European Journal of Surgery Volume 164, Issue 12, pages 965–969, December 1998.

<sup>209</sup> Klosterhalfen B, Klinge W, Schumpelick V: Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Biomaterials. 1998 Dec;19(24):2235-46.

Costello et al., in 2007, reported that polypropylene is more susceptible to degradation due to oxidation caused by inflammatory response. Using Scanning Electron Microscopy (SEM), degradation could be seen in PP in the form of cracks and peeling.

Dr. Donald Ostergard, a urogynecologist and founder of AUGS, created a presentation titled *"Polypropylene is Not Inert in the Human Body"* in which he described degradation of in vivo polypropylene.

"Degradation occurs by oxidation";

"A large surface area incites more inflammation";

"This results in more oxidation since more macrophages are present";

Macrophages secrete hydrogen peroxide and hypochlorous acid to oxidize the mesh";

"Mesh may become brittle."

In a 2010 article by Clave et al., 100 pelvic floor explants were analyzed. Results showed an over 20% rate of degradation from the implants. They concluded that *"for transvaginal surgery, clinical experience indicates the use of low density, large pore implants knitted from a monofilament to facilitate tissue integration, and decrease the inflammatory response....not all types of PP implants degraded equally."* It should be noted that the lead author, Henri Clave, holds an educational position for Ethicon Europe.

In a 2013 article by Wood et al, it was determine that polypropylene material will degrade in vivo due to its exposure to foreign body responses.<sup>211</sup>

As polypropylene degrades, the inflammatory response increases and intensifies.<sup>212,213,214</sup> The abraded fiber surface increases the surface area of the mesh, provides multiple areas that can effectively harbor bacteria, and creates a *"barbed-wire"* effect, all of which lead to an increased risk of an enhanced and chronic inflammatory response, as well as chronic infections due to bacterial proliferation at the mesh surface.

The literature and internal Ethicon studies demonstrate clearly that Ethicon's surgical polypropylene meshes oxidize, degrade, crack and peel in human tissue.<sup>215</sup>

<sup>210</sup> Klosterhalfen B, Klinge W, Hermanns B et al: Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. [ABSTRACT] Chirugr 2000;71:43-51.

<sup>211</sup> Wood, A. et al. Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. J Mater Sci Mater Med 24, 1113-22 (2013).

<sup>212</sup> Mamy L, Letouzey V, Lavigne J et al: Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J. 2011 Jan;22(1):47-52.

<sup>213</sup> Boulanger L, Moukerrou M et al. Bacteriological analysis of meshes removed for complications after surgical management of urinary incontinence or pelvic organ prolapse. Int Urogynecol J (2008) 19:827-831

<sup>214</sup> Bellon J, Honduvilla N, Jurado F et al: In vitro interaction of bacteria with polypropylene/ePTFE prostheses. Biomaterials. 2001 Jul;22(14):2021-4.

<sup>215</sup> Liebert T, Chartoff R, Costgrove S. Subcutaneous Implants of Polypropylene Filaments. J.Biomed. Mater. Res. 1976; 10:939-951, Williams D. Review Biodegradation of surgical polymers. Journal of Materials Science. 1982;



Dr. Iakovlev has published numerous articles showing and explaining the degradation and surface cracking of polypropylene explants using histological and transmission electron microscopy approaches.<sup>216</sup>

Not only is this information widely known and accepted in the medical and scientific communities, but it was also known to Ethicon before and at the time of launch of the Prolift System. There are Ethicon studies dating back as far as 1983 using test methods nearly identical to Dr. Iakovlev's showing in vivo degradation of the Prolene polypropylene material.<sup>217</sup> Ethicon conducted additional studies in 1985 (dog study) and in 1987 (human explants); both showing in vivo degradation and cracking of the polypropylene materials.<sup>218</sup>

It is my opinion, to a reasonable degree of medical and scientific certainty that not only does polypropylene degrade in the human body, but failure to warn doctors and patients that Prolift mesh would degrade in human tissue was inexcusable and dangerous to patients and further demonstrates a pattern of Ethicon's refusal to truthfully and accurately communicate known risks and complications of permanent implantation of its Prolift mesh in patients.

#### **L. Pain Syndromes**

Persistent pelvic pain (lasting more than 12 weeks after surgery) such as vaginal pain, groin pain, pain with walking, pain with sitting, and pain with sexual activity has been reported as high as 20% of women following Prolift POP repair. Mesh-induced pelvic and vaginal inflammation can lead to nerve irritation due to the mechanical irritation of the mesh and surrounding tissues on the pelvic nerves. This process leads to chronic pain syndromes involving the pelvis, vagina, and buttocks.

The etiology of pain syndromes after Prolift surgery is multi-factorial, given the anatomy and physiology of the pelvic areas affected by the Prolift procedure and the consequences of permanent mesh placement. Chronic pelvic and buttock pain can occur following the implantation of the Prolift system. This is due to a number of reasons including the blind trocar passes through multiple large pelvic muscles, chronic inflammation, contraction of the mesh, nerve entrapment and disruption due to excessive scarring and scar plate formation, nerve trauma and dissection due to surgical implantation of a mesh with sharp edges that curls, ropes, deforms and forms painful ridges in the vagina and surrounding organs. Any or all of the pelvic muscles can be permanently injured or inflamed secondary to the act of the trocars passing through them

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17:1233-1246, Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, ASAIO Journal, 44 (1998) 199-206, Wood, et al. Materials Characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. J Mater Sci: Mater med (2013) 24:1113-1122, DEPO.ETH.MESH.00000367, ETH.MESH.09557798, ETH.MESH.15144988, ETH.MESH.00874032, ETH.MESH.07192929, B. Klosterhalfen presentation "What can we learn from explanted meshes?", Depositions of Thomas Barbolt and Daniel Burkley and exhibits thereto

<sup>216</sup> Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. Virchows Archiv 2014, 463(1): 35; Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. Virchows Archiv 2014, 463(1): 35

<sup>217</sup> ETH.MESH.15955438

<sup>218</sup> DEPO.ETH.MESH.00004755; ETH.MESH.11336474; ETH.MESH.13334286

and/or secondary to the inflammation caused by the mesh contraction. As a result of this muscular pain, it is not unusual for the woman to be greatly limited in her activities and have a significant negative impact on her QOL. For most of the chronic pain syndromes there is no consistently successful treatment.<sup>219,220,221</sup>

On December 1, 2005, in the notes from the Prolift Round Table Discussion, buttock pain was identified as a complication,<sup>222</sup> but Ethicon did not list postoperative buttock pain as a risk in the original or revised Prolift IFU. In February 2006, Dr. Michel Cosson (a French surgeon who was part of the team that developed the TVM procedure used with the Prolift system) advised Ethicon that a statement should be added to the Prolift IFU about the complication of postoperative pain. However, the Prolift IFU was not revised at that time. The term "pain" was later added to the list of potential adverse reactions, in October 2009. Therefore, Ethicon intentionally withheld information about postoperative pain as an adverse reaction after the Prolift procedure for 3 ½ years.<sup>223</sup> Furthermore, merely listing the word "pain" woefully underdescribes the complex and chronic pain syndromes.

### M. Sexual Dysfunction

Painful sexual activity (dyspareunia) and any functional sexual disorder which makes satisfactory sexual activity for the female and her partner painful will have a significant negative impact upon a patient's QOL. Unfortunately, this condition, as well as any other sexual QOL issues, are frequently not studied, are underreported when studied, or completely ignored in the medical literature. The true impact and negative effect on QOL from embarrassment, loss of intimacy, pain, and depression for a woman affected with this condition cannot be truly estimated; but a vast amount of medical literature exists documenting how impaired sexual function significantly impacts a woman's QOL. Therefore, new-onset, post-mesh POP surgery dyspareunia (de novo) rates are underreported, but the reported rates range up to nearly 20%.<sup>224</sup>

The source of dyspareunia and vaginal pain following Prolift POP surgery is multifactorial. The modalities described above can cause general pain and sexual dysfunction. Additionally, the chronic and progressive nature of mesh contraction causing vaginal shrinkage, shortening and fibrosis (firmness) plays a significant role. This condition continues indefinitely such that many patients currently unaffected become affected with time. Depending on the severity of vaginal shrinkage and shortening, outcomes can range from mild sexual discomfort to complete loss of sexual function and inability to accommodate for intercourse.

Also, many studies report only short-term results of less than one year. It is understood that mesh contraction can take many years to develop and this progressive nature of mesh contraction can lead to a delayed onset of dyspareunia and vaginal/pelvic pain. Therefore, there

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<sup>219</sup> ETH-80647 (Lucente prefers "20 recurrences or erosions over 1 pain patient")

<sup>220</sup> ETH.MESH.00067363

<sup>221</sup> Withagen M Vierhout M, Hendricks J et al: Risk factors for exposure, pain, and dyspareunia after tension-free vaginal mesh procedures. *Obstet Gynecol.* 2011 Sep;118(3):629-36.

<sup>222</sup> ETH-80636-80644

<sup>223</sup> Walji Deposition 3-4, p 294

<sup>224</sup> Walid MS, Heaton RL: Laparoscopic apical mesh excision for deep dyspareunia caused by mesh banding in the vaginal apex. *Arch Gynecol Obstet.* 2009 Sep;280(3):347-50.

are more patients who have been treated with Prolift mesh who have not yet developed dyspareunia, but given enough time, will.<sup>225,226,227,228,229</sup> There is no effective treatment for dyspareunia. Despite all available treatment modalities, it is not uncommon for up to 50% of patients to have permanent pain with sexual activity.

Internal emails and meetings at Ethicon both prior to and after the launch of Prolift demonstrate a failure to address this serious condition either through proper warnings to doctors and patients or in design changes to decrease the risk.<sup>230</sup> Despite its knowledge of this very serious complication, Ethicon elected not to warn of the increased risks to sexually active women, or include the statement regarding the risk of Prolift POP surgery causing “pain with intercourse and pelvic pain.”<sup>231</sup> As a result of this decision, countless women were, and will be, permanently and needlessly forced to suffer lifelong pain and embarrassment by Ethicon’s failure to properly warn of this condition.

#### **N. Frequency of Complications**

There is some confusion and often misleading documentation discussing whether or not a given mesh-related complication is defined as “rare” or not. As mentioned earlier in this report, it is important to note that there is no single, widely-accepted definition for “rare.” The definitions used in the medical literature and by national health plans are similarly divided, with definitions ranging from 1/1,000 to 1/200,000. Based upon these criteria most of the mesh-related complications do not remotely fit the definition of “rare.”<sup>232,233,234</sup> Ethicon defines “rare” as 1/100,000. Ethicon claims that complications due to its mesh products are “rare”. But the percentages of serious complications listed in this report are anything but “rare” and many instances occur greater than 10% (1/10) of the time and in other instances 20% (1/5) or more of the time.

In an article published in 2011, a group of physicians were attempting to create terminology and classifications for complications directly related to the implantation of devices into the pelvic floor. The majority of these physicians stated that they were in some way affiliated with medical device manufacturers. Approximately 84 categories were created, showing the large amount of complications that are directly related to mesh products.<sup>235</sup>

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<sup>225</sup> ETH-80645 – 80651

<sup>226</sup> Walji Deposition 3-8, p398-399

<sup>227</sup> Walji Deposition 3-8, p365-366

<sup>228</sup> Gauld Deposition Rough 4-26, p200

<sup>229</sup> Hinoul Deposition 4-5, p200

<sup>230</sup> ETH.MESH.02017152 2007 Expert Meeting; ETH.MESH.00870466: 2006 Expert meeting; ETH.MESH.01220871 email from Kammerer re: D’Art Conversation with Prof. Jacquetin; ETH.MESH.05448541: Email from Susanne Landgrebe re shrinkage review; ETH-18761: email from Kelly Brown re: Proposal for work with CBAT; ETH.MESH.00130117: Email from Ophelie Berthier re ICS Prolift Abstracts

<sup>231</sup> ETH-80318

<sup>232</sup> Gauld Deposition rough 4-26, p 171, p251

<sup>233</sup> Walji Deposition 3-8, p 477

<sup>234</sup> Hinoul Deposition 4-5, p71

<sup>235</sup> Haylen B, Freeman R, Swift S et al: An International Urogynecological Association (IUGA) / International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) & grafts in female pelvic floor surgery. Int Urogynecol J (2011) 22:3–15.

The Prolift surgical kit and procedures are relatively new and unique surgical tools and surgical procedures for POP. Therefore, there is a learning curve associated with their proper performance. In order to reduce complications, to provide the most appropriate anatomical results, and to maintain normal vaginal and pelvic floor function, it is impracticable if not impossible for treating surgeons to have an advanced knowledge of the range of reported complications if "kept in the dark" by manufacturers of these products.

It does not require vast amounts of medical knowledge and experience nor does it require biostatistical analysis to view complications consistently ranging in the 10-20% range as not "rare." Using common sense and the generally accepted definitions of the medical term "rare," most, if not all of the mesh-related complications are "frequent" or "common", but certainly not "rare." Statements suggesting otherwise are misleading to unsuspecting surgeons and patients.  
236,237,238,239

A consistent pattern of significantly increased complication rates of transvaginal Prolift mesh over traditional no-mesh POP repairs is found throughout the medical literature. These complications also come without demonstrable symptomatic or QOL improvement compared to traditional non-mesh surgery. The complications are not "rare" as stated and otherwise implied in the Ethicon IFU documents regarding Prolift. Some complications require repeat surgical intervention to repair the tissue damaged by the effects of the Prolift mesh. Complications such as pelvic pain, buttock pain, vaginal pain, dyspareunia, and pain with walking and sitting have no known consistently successful treatment.

Unfortunately, due to multiple factors, it is very difficult to know the true incidence and severity of many of the mesh-specific complications, but it is clear that they are often underreported. Ethicon withheld information about the frequency of complications in its planned response to the FDA notification.<sup>240</sup> Instead of making efforts to disseminate the very important safety information contained in the FDA notification, Ethicon deliberately downplayed the notification, and instructed its sales staff to refrain from bringing up the FDA notification with physicians.<sup>241</sup> Such instructions are contrary to Ethicon's duty to provide fair and balanced information to physicians and patients regarding the Prolift System.

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<sup>236</sup> Walji Deposition 3-8, p477

<sup>237</sup> Gauld Deposition rough 4-26, p251

<sup>238</sup> Gauld Deposition rough 4-27, p171

<sup>239</sup> Hinoul Deposition 4-5, p71

<sup>240</sup> ETH-47351 (10-15-2008 email about response to FDA notification "...We would prefer not to give reported complication rate for TVT but instead emphasize our commitment to reporting complications")

<sup>241</sup> ETH-47369 (10-21-08 email from Scott Jones about FDA notification to Field Sales Team ".... Also, please note that you are not to proactively initiate conversations with your customers about this notice. If you are asked about the notice, you should respond with the following statement: The complications stated in the notification are known risks that can occur with surgical procedures of this type and they are included in the labeling for our products. If you have further questions, please contact our Medical Affairs group.")



## VIII. Product Development

### A. Standardized Product & Technique

The attempt at developing a standardized surgical technique for pelvic mesh implantation began with the TVM studies in both the US and France. Ethicon's reasons for proceeding with the launch of Prolift were "supported" by very limited results that were seen during these studies.<sup>242,243,244,245</sup>

At the time of launch, only short-term (6-month) results were available. They saw complication rates that were higher than expected; however, Ethicon continued to list them as "rare." Also, as pelvic floor meshes are implanted as a permanent device, it is inappropriate to consider 6-month results a sufficient representation of efficacy and safety, as complications continue to increase with time, as reported by Miller et al. in 2011.<sup>246</sup> The technique used differed between the initial U.S. and French TVM studies. Although, this technique was not considered to be the "final" procedural guide or device, it was their justification for launching Prolift in 2005. In fact, all Ethicon-sponsored articles reporting TVM findings appear to be flawed and misleading.

Ethicon did not submit a 510k premarket notification application to the FDA before marketing Prolift in March 2005. Ethicon was not permitted to market Prolift Pelvic Floor System until FDA clearance in May 2008.<sup>247</sup> It was sold to surgeons and patients for 3 ½ years without proper FDA clearance. No reasonable surgeon would have used the Prolift System had Ethicon disclosed that they had failed to seek or receive proper FDA clearance for this "revolutionary" surgical technique using a "specially designed" pelvic floor mesh. The fact that Ethicon employees acknowledge in internal communications, as cited herein, that the TVM procedure and surgical technique was a "major mind shift" for pelvic surgeons, makes Ethicon's decision not to seek 510k clearance that much more egregious.

### B. The IFUs for Prolift Contain the Same Indications as for Gynemesh PS.

The Prolift Systems represented something much different from traditional POP surgery repair as they were developed as a kit (with components like Guides/trocars, Cannulas, Retrieval Devices, and pre-cut mesh implants) and as a new procedure with detailed steps.<sup>248,249,250</sup> As such, multiple new issues of safety and effectiveness were introduced with the Prolift System over and above Gynemesh PS, which was sold simply as a sheet of mesh to be used by the physician as the physician deemed was appropriate.

### C. Ethicon Designed Prolift, Not Merely as a Surgical Mesh, but as both a Product *and* a Technique.

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<sup>242</sup> ETH.MESH.02589071

<sup>243</sup> Walji deposition 3-8, p457

<sup>244</sup> Gauld Deposition rough 4-26, p200

<sup>245</sup> Hinoul Deposition 4-5, p200

<sup>246</sup> Walji Deposition p404

<sup>247</sup> ETH-01363 - 01365

<sup>248</sup> ETH-00253 (Gynemesh PS)

<sup>249</sup> ETH.MESH.00095913 – 00095918 (Prolift)

<sup>250</sup> Cosson M, Caquant F et al. Prolift for Pelvic organ prolapse surgical treatment using the TVM group technique - a retrospective study of 687 patients. (ABSTRACT)

Ethicon obtained United States patents for:

- The process of creating a surgical mesh of PP monofilament yarn;<sup>251</sup>
- The shape of the mesh implants and the procedures for placing the mesh implants;<sup>252</sup>
- The system and method for mesh placement (guide, cannula, retrieval, steps of the surgery);<sup>253</sup> and,
- The packaging (precut mesh, etc.).<sup>254</sup>

All of these patents are further evidence of the unique nature of the Prolift product and surgical technique. Ethicon also consistently refers to the “*Prolift procedure*” in its materials, including the IFU and the Prolift surgical technique guide.<sup>255,256,257</sup>

#### **D. Faulty Prolift Product Design and Resultant Complications**

There is a scientific correlation between the biophysical characteristics of Prolift mesh and the documented mesh-specific complications of vaginal erosion, extrusion, inflammation, and infection with resultant chronic pain in the pelvis and vagina.<sup>258,259</sup> As a classification for pelvic floor meshes has not been created, the classifications for hernia meshes have often been used. Amid wrote an article in 1997, determining that hernia meshes should have a pore size greater than 75 microns in order to allow for macrophages to clear bacteria; however, his classification did not address scar plating and contraction, and was outdated shortly after publication because “macroporous” or “large pore meshes” did not exist prior to the development of Vypro (Ethicon) mesh, first marketed in 1998. An article was recently published by Klinge et al., which requires a textile porosity greater than 60% in order to be considered ‘large pore,’ and therefore, allowing for an appropriate level of tissue integration. It is also noted in that publication as well as other scientific literature and numerous Ethicon documents (including Ethicon Medical Affairs Director, David Robinson’s draft Clinical Expert Report for Prolift +M) that the pore size of mesh implants needs to be greater than 1mm in all directions in order to allow for proper tissue integration. Inadequate tissue integration caused by inadequate porosity and pore size can reasonably be expected to result in the development of a rigid scar plate, potentially leading to erosion, nerve entrapment, pain syndromes, dyspareunia, and loss of elasticity and mesh contraction. As early as 1998, Ethicon knew and stated repeatedly throughout internal documents that pore size less than 1 mm would result in fibrotic bridging and increased safety risks to patients.

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<sup>251</sup> ETH-07427 - 07433

<sup>252</sup> ETH-07434 – 07494

<sup>253</sup> ETH-07546 - 07609

<sup>254</sup> ETH-07495 - 07545

<sup>255</sup> ETH-00002

<sup>256</sup> ETH-01761

<sup>257</sup> ETH.MESH.00419572

<sup>258</sup> ETH.MESH.02589066-02589068

<sup>259</sup> Kirkemo Deposition 4-18, p135-138

Both during mesh implantation and after, the arms are put under a considerable amount of strain, which may ultimately lead to mesh curling, roping, and/or pore deformation. This creates an even further enhanced state of inflammatory response in the pelvic area.<sup>260,261</sup>

Once a pelvic floor mesh is implanted, the surgeon is unable to see the mesh to know whether it has stayed in a flat position. Wrinkling or curling of the mesh will also prevent adequate tissue in-growth and lead to fibrotic bridging, and increased contraction, and thus, the cascade of chronic inflammatory events, further increasing the risk of complications.

As my practice has evolved to spending almost half my clinical time treating mesh-related complications related to both incontinence slings and POP mesh, I can say that mesh curling, roping, fraying and deforming is a real problem with these meshes. The Prolift mesh, especially the arms, curls and ropes and increases the risk of the cascade of symptoms as set forth throughout this report, with erosion/extrusion, chronic pelvic pain, dyspareunia, organ dysfunction and the need for painful multiple revision surgeries being at the top of the list.

#### **E. Insufficient Prolift Preoperative Guides**

Ethicon is responsible for ensuring the safety and effectiveness of products for its intended use and function. Ethicon was marketing not only a new product but also a new surgical procedure.

Ethicon claimed in marketing materials that Prolift was appropriate for almost all patients,<sup>262,263</sup> but it had no clinical evidence to support these claims.

Ethicon claimed that Prolift was appropriate for patients with recurrent prolapse,<sup>264,265</sup> but it was forced to admit that it had no clinical evidence to support this claim during FDA review. Therefore, Ethicon agreed to remove this claim from its labeling.<sup>266</sup> Despite this “agreement,” Ethicon continued to make this claim in online Prolift DTC advertising.

Ethicon claimed that a sling procedure to treat SUI could be performed at the same time as the Prolift procedure.<sup>267</sup> However, Ethicon had no clinical evidence to support this claim. In fact, Ethicon had received feedback from experienced Prolift surgeons that the effectiveness of sling procedures was dramatically decreased when performed at the same time as the Prolift procedure.<sup>268</sup> Despite this, Ethicon apparently never studied this issue and never provided this information to surgeons or patients (i.e., that the effectiveness of slings may be decreased with concomitant Prolift procedure).

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<sup>260</sup> Kirkemo Deposition 4-18, p135-138, p150

<sup>261</sup> Hinoul Deposition 4-5, p506-507

<sup>262</sup> ETH-00260

<sup>263</sup> ETH-00264

<sup>264</sup> ETH-00260

<sup>265</sup> ETH-00264

<sup>266</sup> ETH-01321

<sup>267</sup> ETH-00258

<sup>268</sup> ETH-80289 (Email from Steele to Bonet dated 5-10-2006: “decreased efficiency in TVT procedures when treating concomitantly with Prolift. [Dr.] LaSala has had >50% failure rate...”)

Ethicon claimed that pain is a symptom of POP,<sup>269,270,271</sup> but they had received feedback from experienced clinicians that pain is not a typical symptom of POP.<sup>272,273</sup> Their marketing materials implied that patients with preoperative pain due to prolapse experienced resolution of the pain after Prolift. However, they had received feedback from experienced Prolift surgeons that patients with preoperative pain often experienced dramatic exacerbation of pain *after* the Prolift procedure.<sup>274,275</sup> Despite this feedback, Ethicon apparently never specifically studied this issue. Ethicon never provided guidance to surgeons or patients regarding the appropriate evaluation and management of patients with pain and prolapse.

Ethicon also marketed to overweight and elderly patients, claiming the procedure was appropriate for them;<sup>276,277,278</sup> but, this claim was never studied and thus, Ethicon had no clinical evidence to support claims that Prolift was a reasonable and appropriate procedure for overweight or elderly patients.

Ethicon stated in the IFU for the TVT (Tension-Free Vaginal tape for urinary incontinence) product line that these products should not be used on patients who are on anti-coagulation therapy (blood thinners such as aspirin, Coumadin, Plavix®). This is because of the blind trocar passages (one on each side) and the inherent bleeding risk this presents. However, the Prolift procedure involves up to six (6) blind trocar passes, and despite anti-coagulation patients' increased risk of bleeding with these trocar passes, Ethicon chose not to warn against this risk in its original Prolift IFU.<sup>279</sup> Although working drafts of the original IFU contained the statement, "*Do not use the Gynecare Prolift Pelvic Floor Repair Systems in patients who are on anti-coagulation therapy,*"<sup>280</sup> this statement was subsequently deleted.<sup>281,282</sup> Ethicon eventually revised the IFU to say that patients on anticoagulation should be "*carefully managed.*"<sup>283</sup>

#### **F. Inadequate Prolift Pelvic Floor System Surgical Training**

A marked difference exists between the Prolift Pelvic Floor System (both product and procedure) and the traditional non-mesh POP repair surgery. This fact was emphasized in Ethicon's product evaluations *before* Prolift was commercially available and in feedback *after* the product was marketed. Because of the new technique developed with this product, Ethicon

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<sup>269</sup> ETH-00255 - 00256

<sup>270</sup> ETH-00264

<sup>271</sup> ETH-48130

<sup>272</sup> ETH-85678 (Email from Dr. Butrick to David Robinson: "POP does not cause pain!!!")

<sup>273</sup> Kirkemo Deposition 4-18, p97-98

<sup>274</sup> ETH-85676 (Butrick to Robinson, "I sure am getting tired of seeing these pts with bad myofascial pain after Prolifts...")

<sup>275</sup> ETH-85678 (slide from Butrick, "The aggressive surgery flares the pre-existing myofascial pain...")

<sup>276</sup> ETH-00264

<sup>277</sup> ETH-07712

<sup>278</sup> ETH-48130

<sup>279</sup> ETH-65877-65884

<sup>280</sup> ETH-16986

<sup>281</sup> ETH-17061

<sup>282</sup> Hinoul Deposition 4-6, p408-410

<sup>283</sup> ETH.MESH.00095913



recommended advanced training for surgeons prior to performing the Prolift procedures.<sup>284,285,286,287</sup>

Surgeon selection criteria for advanced training was initially focused on highly-skilled and experienced surgeons. Despite their advanced skill level, many of the surgeons had to be re-trained shortly after Prolift's launch.<sup>288</sup>

Despite Ethicon being provided feedback regarding the inadequacy of the training/trainees for the Prolift procedures, Ethicon representatives pushed the envelope on training. Ethicon did not want a repeat of the transobturator stress urinary incontinence inter-company competition where Ethicon was in a catch-up position from launch.<sup>289,290</sup>

In marketing materials, Ethicon claimed that Prolift was appropriate for almost all patients but it had no clinical evidence to support these claims.<sup>291,292</sup>

Hydrodissection is a surgical step used to create a space between the vagina and the rectum and/or bladder. The purpose of this step is to identify and surgically enter the rectovaginal/vesicovaginal space more easily and to reduce the risk of injury to the adjacent rectum and/or bladder. This step would seem even more important given the differences between vaginal dissections in Prolift procedures versus traditional procedures. However, the Prolift IFU makes no mention of vaginal wall hydrodissection. The Surgical Guide merely lists hydrodissection as a bullet-point item "to be considered as optional."<sup>293</sup> However, from internal documents and feedback from surgeons, Ethicon understood the importance of hydrodissection to minimize complications for surgeons unfamiliar with the vaginal dissection required for the Prolift procedure. Subsequently, there were many surgeons unaware of the potential importance of this potential surgical step.<sup>294,295,296,297,298,299,300,301,302,303,304,305</sup>

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<sup>284</sup> See ETH-83318

<sup>285</sup> See ETH-62214

<sup>286</sup> See ETH-83323

<sup>287</sup> See ETH-01624

<sup>288</sup> ETH-62214 (Email from Vie [Education Development Manager] dated 5-17-2005: "...16 of the 84 [surgeons trained as of May 3] have needed to be retrained (19%)...")

<sup>289</sup> ETH-83193 – 83194 (email from Miller [proctor] dated 12-10-2005 regarding preceptorship: "...I thought a couple of those guys were going to poke somebody's eye out.")

<sup>290</sup> ETH-83318 (email from Sweatt [District Manager] dated 6-27-2006: "...The reps push the envelope on training because they don't want to see a repeat of the obturator wars, where we were in a catch up position from launch. Our current labs don't really discuss Gynemesh, which is what most doctors should in fact be using at this point.")

<sup>291</sup> ETH-00260

<sup>292</sup> ETH-00264

<sup>293</sup> ETH.MESH.00419573

<sup>294</sup> ETH-74435 ("key for minimizing erosion risk")

<sup>295</sup> ETH-02707-02708 ("...critical to maintaining low rates of mesh exposure seen by experienced...users.")

<sup>296</sup> ETH.MESH.PM.000019

<sup>297</sup> ETH.MESH.00419571-00419600

<sup>298</sup> ETH-20085

<sup>299</sup> ETH-60151 ("Hydrodissection is key in helping...")

<sup>300</sup> ETH.MESH.00158295 (Prolift Forums and Round Table Summary of experienced Prolift surgeons – "Hydrodissection was identified as a key procedural step")

<sup>301</sup> ETH-19943

Initially, Ethicon provided no guidance and subsequently provided inadequate guidance to surgeons as to the necessity of performing a cystoscopy (a procedure looking into the bladder at the time of Prolift Anterior and Prolift Total POP surgery).<sup>306,307,308,309,310,311</sup> Nor did Ethicon discuss the critically important issue of timing of the cystoscopy in conjunction with the Prolift procedures. A cystoscopy is an essential step following the blind passage of the Prolift. Guides/trocars to detect if there has been any inadvertent damage to the bladder. The surgeon can reassess the bladder following trocar removal to determine the most appropriate management for the patient, including cancelling the planned mesh insertion, as recommended by the Prolift surgical guide.<sup>312,313</sup> In the original Prolift IFU, there was no information regarding the need for cystoscopy or the appropriate timing of an intraoperative cystoscopy to detect potential bladder injury. Although the original draft version of the IFU did have a statement regarding intraoperative cystoscopy, the final version of the original IFU omitted such recommendation.<sup>314,315</sup>

Prolift surgeons recommended that cystoscopy be performed in all Prolift procedures.<sup>316,317,318,319,320,321</sup> However, Ethicon ignored this feedback and did not place this requirement in the IFU or the Surgical Guide.

Ethicon ignored a request by the FDA that cystoscopy be recommended. Instead, Ethicon added a statement in the Prolift IFU that cystoscopy was “optional.”<sup>322,323</sup>

Ethicon understood that at many hospitals, surgeon credentialing for cystoscopy performance was limited by specialty, especially limiting gynecologists.<sup>324</sup> Thus, if cystoscopy were stated as a requirement in the Prolift IFU, surgeons without credentialing for cystoscopy (many gynecologists) would not be credentialed to perform Prolift surgery independently. So, in

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<sup>302</sup> ETH-08028

<sup>303</sup> ETH.MESH.00008084

<sup>304</sup> Robinson Deposition 3-13, p193-196

<sup>305</sup> Henderson Deposition p146

<sup>306</sup> ETH-02711

<sup>307</sup> ETH-80643

<sup>308</sup> ETH-19622

<sup>309</sup> ETH-19944

<sup>310</sup> ETH-02713

<sup>311</sup> ETH-19645

<sup>312</sup> ETH.MESH.00419571 – 00419600

<sup>313</sup> Hinoul Deposition 4-6, p609-610

<sup>314</sup> ETH-62799

<sup>315</sup> ETH-62803 - 62808

<sup>316</sup> ETH-02711

<sup>317</sup> ETH-80643

<sup>318</sup> ETH-19622

<sup>319</sup> ETH-19944

<sup>320</sup> ETH-02713

<sup>321</sup> ETH-19645

<sup>322</sup> ETH-01242 – 01248 (12-20-2007 Communication from FDA to Ethicon regarding the Prolift and Prolift-M 510K's requesting “Please add a warning...”)

<sup>323</sup> ETH-01761 2-22-2008 response by Ethicon stating that they would revise to say that “Cystoscopy may be performed...”

<sup>324</sup> Henderson Deposition 10-5, p457

order to broaden their market to surgeons not credentialed in cystoscopy, Ethicon chose to only list cystoscopy as an option, at the expense of patient safety.

Reducing the size (trimming) of the Prolift mesh is recommended in the Guide.<sup>325</sup> However, there is no explanation given to the implanting surgeon as to the standardization of when trimming is “*required*,” what constitutes “*small reductions*,” nor what constitutes a “*proper fit*” of the anterior and posterior mesh implants. The Guide only states in one place that, “[i]t is recommended to avoid large vaginal excisions...”<sup>326</sup> No other guidance is given by Ethicon despite the fact that their consulting surgeons expressed to them how important it is to consider the anticipated amount of mesh contraction in determining whether and how much vaginal trimming to perform.<sup>327,328</sup>

The Prolift POP Procedure is not truly “*standardized*.” The first sentence of the Prolift Guide claims that, “[t]he objective of the Prolift procedure is to achieve a complete anatomic repair of the pelvic floor defects in a standardized way.” However, one of the most important concepts of the Prolift procedure is “*tension-free*” placement of the mesh implant, which cannot be standardized given both the patient-to-patient and the surgeon-to-surgeon variability in detecting this.<sup>329</sup>

Ethicon representatives acknowledge that there is no standardized means of determining whether Prolift mesh is in fact, “*tension-free*.” After four years of selling and training the Prolift procedures, Ethicon still had problems training surgeons on standardizing the “*tension-free*” aspects of the procedure.<sup>330,331,332</sup>

It is generally accepted that the correct positioning and tensioning of the mesh and mesh arms is an essential surgical step to prevent needless complications. However, Ethicon provides no standardized instruction on how to ensure that this critical step is performed correctly. Ethicon documents describe fixation of Posterior Straps (Transgluteal or vaginal approach). Two perineal incisions bilaterally and the cannulas are passed through gluteal area to traverse the sacrospinous ligament and exit into the vaginal incision. Each of the two posterior straps is shortened and fixed directly to the sacrospinous ligament bilaterally.<sup>333</sup>

However, there is no guidance provided by Ethicon to the surgeons regarding: (a) how to decide whether sacrospinous fixation of the posterior straps is necessary or preferred over the transgluteal approach; (b) how to decide the proper length for trimming the posterior straps in a “*standardized*” manner; and (c) how to determine best means of affixing the shortened posterior straps to the sacrospinous ligaments in a “*standardized*” manner.

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<sup>325</sup> ETH.MESH.00419584 - 00419585

<sup>326</sup> ETH.MESH.00419572

<sup>327</sup> ETH-80641 (“Mesh will contract up to 30%.”)

<sup>328</sup> Robinson Deposition 3-13, p260

<sup>329</sup> ETH.MESH.PM.000019

<sup>330</sup> ETH-49659

<sup>331</sup> Hinoul Deposition 4-5, p506-507

<sup>332</sup> Kirkemo Deposition 4-18, p135-135, p150

<sup>333</sup> ETH.MESH.00419582

Positioning of the anterior segment of the Prolift is intended to be placed under the bladder in lateral contact with the arcus tendineus fascia pelvis.<sup>334,335</sup> But, the Surgical Guide does not give any guidance on how to accomplish this in a standardized manner, raising a number of questions regarding technique to accomplish this step.

Positioning of the posterior segment of the Prolift is intended to be placed above the rectum in lateral contact with the superior surface of the levator ani muscles.<sup>336 337 338 339</sup> But, the Surgical Guide does not give any guidance on how to accomplish this in a standardized manner, raising a number of questions regarding technique to accomplish this step.

Adjusting the position and the tension of the Prolift is addressed in the Guide.<sup>340</sup> But it gives no guidance on how to determine: (1) when and whether “further adjustments of tension and position” will be neither necessary, nor (2) the magnitude of “further adjustments” in a “standardized” manner.<sup>341 342</sup> Again, in 2009, more than four years after the launch of Prolift, Ethicon was made aware of the difficulty in teaching “tension-free” placement in a “standardized” manner.<sup>343</sup> Since mesh arm tensioning and positioning are such an essential aspect to reducing complications, it is wholly unacceptable for such a critical surgical procedure to be left without clear instructions for the surgeon.

A surgeon would reasonably expect Ethicon’s Surgical Guide to provide useful guidelines on critical maneuvers and measures to avoid needless complications. The absence of recommendations and potential complications would reasonably imply to a surgeon a lack of importance of key surgical steps. It is important to keep in mind that Ethicon developed and patented the TVM technique and surgical procedure, which was, according to Ethicon, a “major mind shift” in urogynecological surgery. At a minimum, Ethicon should have provided key technique guidelines, warnings, and recommendations based upon high volume surgeons’ experience and feedback such as:

- Warnings regarding the increased risk of urinary incontinence following Prolift Anterior and Prolift Total repairs.
- Need for hydrodissection of vaginal wall.
- Critical role of permanent suture at base of cervix.
- Importance of proper vaginal wall dissection to prevent complications.
- Importance of mesh trimming and need for it to be done properly.
- The implications of performing a uterine preserving repair vs. hysterectomy vs. post-hysterectomy Prolift Total POP repair.

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<sup>334</sup> ETH.MESH.00419584

<sup>335</sup> ETH.MESH.PM.000019

<sup>336</sup> ETH.MESH.00419585

<sup>337</sup> ETH.MESH.PM.000019

<sup>338</sup> Hinoul Deposition 4-5, p506-507

<sup>339</sup> Kirkemo Deposition 4-18, p135-135, p150

<sup>340</sup> ETH.MESH.00419584 – 00419585

<sup>341</sup> Hinoul Deposition 4-5, p506-507

<sup>342</sup> Kirkemo Deposition 4-18, p135-135, p150

<sup>343</sup> ETH-49659 (email dated 8-10-2009 from Kirkemo: “A real misconception exists in the community.... We really need to think about how to change our teaching...”)

- Recommendations to accurately pass the transobturator trocars blindly into the proper anatomic locations.
- Recommendations regarding the importance of feeding the mesh without twisting through the Prolift Cannula, resulting in preventable complications if this step is incorrectly performed
- Recommendations regarding the crucial importance of proper mesh tensioning, resulting in preventable complications if this step is incorrectly performed.
- Essential need for cystoscopy to rule out inadvertent bladder perforation.

Mesh exposure and bladder injury are common complications, yet there is inadequate guidance in the Surgical Guide on managing these complications. An absence of a description and guidance in the management of these complications minimizes the frequency and magnitude of these complications to a surgeon.

Dyspareunia, vaginal pain, and pelvic pain are common complications following Prolift POP procedures, yet there is inadequate information in the Surgical Guide explaining the lack of a safe and effective method to treat these complications. The absence of this information minimizes the frequency and magnitude of these complications to a surgeon.<sup>344 345</sup>

#### **IX. FALSE AND MISLEADING STATEMENTS BY ETHICON**

##### **A. Prolift mesh provides “long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse”.<sup>346</sup>**

Clinicians reading this statement would reasonably assume that Ethicon possessed evidence from clinical trials that Prolift Pelvic Floor Repair System had demonstrated “long-lasting” effectiveness. However, Ethicon had no such evidence as of March 2005, when marketing of Prolift Pelvic Floor Repair System was initiated.<sup>347,348,349</sup> Ethicon still had no such evidence as of August 2007 to May 2008, when the FDA review of Prolift Pelvic Floor Repair System was ongoing. In September 2007, Ethicon informed the FDA that “no clinical investigations were conducted on the use of Prolift Pelvic Floor Repair System.”<sup>350</sup> Therefore, Ethicon's use of the term “long-lasting” had no factual basis. By claiming that Prolift produces “stabilization of fascial structures of the pelvic floor in vaginal wall prolapse,” Ethicon implies that studies had been performed to directly assess the anatomic and physiologic effect of the Prolift system on the pelvic floor. Clinicians reading such a statement would reasonably and incorrectly assume that studies had demonstrated a direct and beneficial effect of Prolift placement on fascial structures that provide pelvic floor support. However, Ethicon had no such evidence at the time marketing of Prolift was initiated in March 2005.

<sup>344</sup> ETH.MESH.00419571 - ETH.MESH.00419600

<sup>345</sup> ETH.MESH.00067363

<sup>346</sup> ETH.MESH.02589071

<sup>347</sup> Walji Deposition p300, p457,

<sup>348</sup> Gauld Deposition rough 4-26, p200

<sup>349</sup> Hinoul Deposition 4-5, p200

<sup>350</sup> ETH-00929 - 00930



In January 2005, Ethicon's own internal Clinical Expert Report on Prolift stated, "... in vivo forces and exerted strains on pelvic floor repairs during the postoperative period are not known."<sup>351 352 353</sup> Years after the Prolift was launched, Ethicon scientists still continued to search for answers regarding the estimated pelvic forces and how to develop a mesh that would compensate those forces. Because the forces on pelvic floor repair were unknown, there would be no way of knowing whether Prolift Pelvic Floor Repair System adequately compensated such forces. Other internal Ethicon documents confirm their conclusion that a lack of knowledge of pelvic floor forces leads to patient complications and that Prolift mesh was not designed to compensate these forces.<sup>354</sup>

**B. Prolift Mesh had "*bi-directional elastic property*".**<sup>355</sup>

The Gynemesh PS mesh used in the Prolift Pelvic Floor Repair System does not stretch significantly. This is a direct contradiction to the claim that the Gynemesh PS mesh used in Prolift has elasticity of any kind, bidirectional or otherwise. Indeed, Ethicon eventually deleted the claim of bidirectional elasticity from the Prolift Pelvic Floor Repair System IFU due to lack of evidence.<sup>356</sup>

By claiming that the Gynemesh PS mesh used in Prolift has bidirectional elasticity, Ethicon implied that studies have been performed to prove that Prolift possesses these elastic design characteristics when used for the surgical treatment of vaginal prolapse. Clinicians reading such a statement would reasonably and incorrectly assume studies had demonstrated adaptation of the mesh to the stresses normally encountered by the unique movement of the vagina. Clinicians would reasonably conclude that, by having elastic properties in two directions, the mesh would allow for expansion of the vagina, which normally occurs during sexual activity, permitting comfortable penile penetration and thrusting of vaginal intercourse. However, Ethicon could produce no such evidence, despite making the claim of bidirectional elastic property of its meshes since 1985 for Mersilene mesh, Prolene Soft mesh, and Gynemesh PS mesh.

Ethicon had no such evidence that Gynemesh PS mesh in Prolift Pelvic Floor Repair System had bidirectional elastic properties at the time the marketing of Prolift was initiated in March 2005. Ethicon had no such evidence that Gynemesh PS mesh in Prolift had bidirectional elastic properties between August 2007 and May 2008, when the FDA review of Prolift was ongoing.<sup>357 358 359 360</sup>

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<sup>351</sup> ETH-07156

<sup>352</sup> ETH.MESH.05237872 Mesh Properties – How important are they?

<sup>353</sup> ETH.MESH02227224 Thunder MGPP decision meeting

<sup>354</sup> ETH.MESH.02185584 Biomechanical Considerations for Pelvic Mesh Design; ETH.MESH.03753245 BIOMECHANICS

<sup>355</sup> ETH-00002

<sup>356</sup> ETH-00943

<sup>357</sup> ETH.MESH.00922443 - 00922445

<sup>358</sup> ETH.MESH.00869985

<sup>359</sup> ETH.MESH.00869987

<sup>360</sup> ETH.MESH.02589077 - 02589078

The FDA requested that Ethicon either remove the statement or provide evidence to support it.<sup>361</sup> On September 20, 2007, Ethicon admitted that they had no evidence to support the claim that the Gynemesh PS mesh in Prolift had bidirectional elastic properties.<sup>362,363, 364</sup> Nevertheless, the baseless claim that Gynemesh PS mesh in Prolift Pelvic Floor Repair System had bidirectional elastic properties remained in the Prolift IFU until 2009.

One of the inventors of the TVM technique as well as a number of other leading scientists and surgeons have attempted to determine the mesh requirements necessary to account for the unique nature of the variability in pelvic and vaginal tissues in terms of elasticity, stretchability, and anisotropy and have been unsuccessful in their studies to adequately define and characterize these parameters in order to define the material characteristics that would properly mimic the pelvic floor environment.<sup>365 366</sup>

### C. Prolift Mesh “remains soft and pliable”.

Ethicon’s claim that the Gynemesh PS mesh used in Prolift Pelvic Floor Repair System remains soft and pliable postoperatively implies that studies have been performed to document this mesh characteristic when used for the surgical treatment of vaginal wall prolapse.<sup>367 368 369</sup>  
<sup>370 371</sup> Clinicians reading such a statement would reasonably and incorrectly assume studies had been performed, which demonstrated the softness and pliability of the mesh after its placement in the vagina. Clinicians would reasonably conclude that mesh characteristics of softness and pliability would not interfere with sexual function after Prolift placement. However, Ethicon was well aware that mesh contraction occurred to some extent in all cases after Prolift placement. In many cases, mesh contraction occurred to the extent of causing complications, including chronic pain, pain with mesh palpation, vaginal rigidity, and dyspareunia. Ethicon was well aware of mesh contraction because of its experience with Prolene mesh and Prolene Soft mesh used for hernia repair.<sup>372</sup>

In addition, Ethicon had no evidence to support the claim that the Prolift “mesh remains soft and pliable” when used for the surgical treatment of vaginal wall prolapse. Indeed, Ethicon had evidence that directly contradicted the claim that the “mesh remains soft and pliable” from

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<sup>361</sup> ETH-00943

<sup>362</sup> ETH.MESH.00922443 - 00922445

<sup>363</sup> ETH-00938

<sup>364</sup> ETH.MESH.09656632

<sup>365</sup> Gabriel B, Rubod C, Brieu M, Dedet B, de Landsheere L, Delmas V, Cosson M. Vagina, abdominal skin, and aponeurosis: do they have similar biomechanical properties? Int Urogynecol J. 2011 Jan;22(1):23-7. Epub 2010 Aug 27.)

<sup>366</sup> Cosson M, Lambaudie E, Boukerrou M, Lobry P, Crépin G, Ego A. A biomechanical study of the strength of vaginal tissues. Results on 16 post-menopausal patients presenting with genital prolapse. Eur J Obstet Gynecol Reprod Biol. 2004 Feb 10;112(2):201-5

<sup>367</sup> ETH.MESH.00067357 (Lucente Webinar: “... the things that we all worried about tissue healing and comfort; the 2 things that, again, have plagued us all along using an implant, erosion and discomfort...”)

<sup>368</sup> Walji Deposition p471-472

<sup>369</sup> Robinson Deposition 3-14 p683-684

<sup>370</sup> Kirkemo Deposition 4-18, p246-249

<sup>371</sup> Ciarrocca Deposition 3-29, p264-266

<sup>372</sup> ETH-80646

several sources, including physician experts,<sup>373</sup> internal documents related to Prolift + M (known as “Project Lightning”) development,<sup>374</sup> and Ethicon-supported animal<sup>375</sup> and clinical studies.<sup>376</sup> Ethicon’s French Medical Director, Axel Arnaud, stated that the mesh remaining “soft and pliable” after implantation was “an illusion.”<sup>377</sup>

As of these key time periods (2005, 2007), there was abundant evidence in the scientific literature regarding mesh rigidity, contraction, shrinkage, fibrosis due to mesh foreign body reaction leading to lack of tissue in-growth, lack of vascularization, and scar plate formation. The origin of synthetic mesh contraction in the human body and in animal models has definitely shown that no mesh is inert.<sup>378,379,380,381,382,383</sup> This inflammatory reaction causes free radical synthesis, which then causes oxidation and degradation of polypropylene meshes.

Mesh degradation then causes more inflammation and, subsequently, more mesh contraction. When mesh contraction occurs in the abdominal wall or thoracic wall, it causes multiple conditions such as chronic pain, fibrosis, and infection. Similarly, when synthetic meshes are placed in the vagina for POP procedures, mesh responds the same way. When vaginal mesh contracts, it causes vaginal fibrosis, infection, chronic vaginal pain, chronic pelvic pain, vaginal shortening, vaginal narrowing, vaginal extrusion, adjacent organ erosion and dyspareunia.

**D. “Wound healing is not noticeably impaired” by Prolift Mesh.**

Similar to the Ethicon’s claim regarding the softness and pliability of its mesh, it appears that Ethicon lacked evidence regarding wound healing following the surgical implantation of Prolift. As with noted above, in September 2007, Ethicon informed the FDA that “no clinical investigations were conducted on the use of Prolift Pelvic Floor Repair System”.<sup>384</sup> However, there existed abundant evidence in the scientific literature regarding rigidity, contraction, shrinkage, fibrosis due to mesh foreign body reaction leading to lack of tissue in-growth, lack of vascularization, and scar plate formation. Ethicon’s internal documents have meeting minutes from meetings between Ethicon representatives and their key outside consulting experts wherein the concept of a “chronic wound” that is created around the mesh was discussed.<sup>385</sup> Ethicon was told that the mesh continues to react in the tissues decades after implantation. So for Ethicon to claim that “wound healing is not noticeably impaired” is absolutely false and misleading given the information they had available to them both before and after the launch of Prolift.

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<sup>373</sup> ETH-82320

<sup>374</sup> ETH-77061

<sup>375</sup> ETH-60555 – 60556

<sup>376</sup> ETH-77061

<sup>377</sup> Arnaud depo 11/15/12 68:18-69:13

<sup>378</sup> ETH-80641 (“Mesh will contract up to 30%”)

<sup>379</sup> ETH-80645 – 80651

<sup>380</sup> Hinoul Deposition 4-5, p 132-134, p147-149

<sup>381</sup> Kirkemo Deposition 4-18, p138, p151-152

<sup>382</sup> Robinson Deposition 3-13, p260

<sup>383</sup> Walji Deposition p465

<sup>384</sup> ETH-00929 - 00930

<sup>385</sup> ETH.MESH.00870466



**E. The Prolift procedure is “minimally invasive”.**

As noted above, Ethicon claimed in its patient brochures that the Prolift procedure was a new and revolutionary minimally invasive procedure. This was inaccurate, and downplayed the invasive nature of the implantation surgery for the Prolift. In fact, Ethicon’s own medical directors described the surgery as a major invasive procedure, yet Ethicon failed to timely correct its labeling. Ethicon’s characterization of the Prolift procedure as minimally invasive is flat wrong, and no doubt falsely reassured doctors and patients.

**F. Prolift Mesh is not “subject to degradation”.**

Ethicon states that the mesh contained in the Prolift System is not “*subject to degradation or weakening by the action of tissue enzymes.*”<sup>386 387 388</sup> There is scientific literature, however, which states just the opposite – polypropylene is not biologically inert and is, in fact, subject to oxidation and degradation. In fact, as stated above in this report, Ethicon’s own internal studies and a significant amount of readily available medical literature specifically concludes that polypropylene mesh incites a specific immune response, creating within the vagina a foreign body reaction that directly causes mesh degradation, mesh contraction, fibrosis, vaginal narrowing, pelvic pain, and dyspareunia.<sup>389 390 391</sup>

Despite its own internal studies and numerous peer-reviewed articles regarding degradation, Ethicon failed to change its IFU, its surgical guide, its patient brochures, or its marketing materials to acknowledge that degradation of the polypropylene in the woman’s pelvic tissues not only would occur but that it would occur at varying degrees over the life of the implant.

**G. Prolift Pelvic Floor Repair Systems “restore normal sexual function”**

Ethicon admits it has no evidence to support claims regarding sexual function after implantation of the Prolift Pelvic Floor Repair Systems.<sup>392 393 394 395 396 397 398</sup> Nevertheless, at the

<sup>386</sup> ETH-01777

<sup>387</sup> ETH.MESH.00570955

<sup>388</sup> ETH.MESH.02589066 - 02589068

<sup>389</sup> Walji Deposition 3-9 p399, p404, p457

<sup>390</sup> Gauld Deposition rough 4-26, p200

<sup>391</sup> Hinoul Deposition 4-5, p200, Hinoul Deposition 4-5, p 132-134, p147-149, Kirkemo Deposition 4-18, p138, p151-152, Robinson Deposition 3-13, p260, Liebert T, Chartoff R, Costgrove S. Subcutaneous Implants of Polypropylene Filaments. J.Biomed. Mater. Res. 1976; 10:939-951, Williams D. Review Biodegradation of surgical polymers. Journal of Materials Science. 1982; 17:1233-1246, Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louise Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, ASAIO Journal, 44 (1998) 199-206, Wood, et al. Materials Characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. J Mater Sci: Mater med (2013) 24:1113-1122, DEPO.ETH.MESH.00000367, ETH.MESH.09557798, ETH.MESH.15144988, ETH.MESH.00874032, ETH.MESH.07192929, B. Klosterhalfen presentation “What can we learn from explanted meshes?”, Depositions of Thomas Barbolt and Daniel Burkley and exhibits thereto

<sup>392</sup> ETH-48281: email from Scott Jones 3-5-2009 “... Apparently, Bos Sci [Boston Scientific] has been talking to doctors about the ‘banding’ effect that occurs with the anterior Prolift.... The banding that customers are telling me occurs at the edge of the mesh near the apex. Regardless of how doctors adjust the mesh, there is still a definite ridge or banding that can be vaginally palpated with our anterior mesh. In fact, during my discussions with Dr. Raul

same time, Ethicon claims in its Patient Information Brochure, "[The Prolift Pelvic Floor Repair Systems] allows for the restoration of sexual function by restoring vaginal anatomy." In fact, as of June 2006, the opposite was shown in a study that demonstrated the number of sexually active patients decreased from 61/90, (68%) at baseline, to 42/90, (47%) at 6 months, and to 40/90, (44%) at 12 months. One-third of patients who were sexually active before surgery became sexually inactive after mesh surgery. The substantial reduction in the number of sexually active patients strongly suggests that many patients abandoned attempts at sexual activity due to dyspareunia or other complications of mesh surgery. Also, it is critical to note that all results described are short term (less than two years).<sup>399</sup>

As is reported in the literature and as I have seen in my own clinical practice, mesh-specific complications, such as mesh contraction leading to dyspareunia, can be delayed many years following implantation. Therefore, the true frequency of dyspareunia is greatly underestimated. Evidence shows that Ethicon had knowledge of impaired sexual function and dyspareunia, but rather than disclosing this knowledge, Ethicon intentionally chose to not disclose the evidence they had in their possession regarding the full extent of complications of sexual dysfunction.<sup>400 401 402 403 404 405</sup>

#### **X. ETHICON'S INSTRUCTIONS FOR USE (IFU) AND KNOWN RISKS RELATED TO THE PROLIFT WERE NOT DISCLOSED**

At the time of the Prolift launch, Ethicon was fully aware of all the risks associated with the Prolift product. Ethicon did not fully or adequately disclose the risks, adverse reactions, or the clinical consequences thereof in the Prolift Instructions for Use (IFU) despite Ethicon's internal awareness of these risks (as demonstrated by extensive internal documentation, ETH.MESH.06372356-ETH.MESH.06372363; ETH.MESH.02026591-02026595) and the deposition testimony of its employees:

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Mendelovici yesterday, he told me that he is so frustrated with the banding effect on the anterior Prolift that he is now modifying his mesh to provide better anterior apical support, and to reduce banding (different modification than Raders or Lucente)... this banding has not been clinically significant for most patients, but the impression in the surgeons eyes is that this is unacceptable, and they will try to avoid this if possible....")

<sup>393</sup> ETH-71307 (3 of 14 patients with unresolved symptoms with palpable mesh banding)

<sup>394</sup> ETH-02689 ("surgical release of mesh banding" was necessary for patients with persistent dyspareunia)

<sup>395</sup> ETH-82419 (Summary of meeting points Sexual function June 2006: "Previous history says that we want to avoid this discussion without a solid case for Prolift....")

<sup>396</sup> ETH-01121 June 2006 "...New onset dyspareunia was reported in 7 patients [of 61 patients] at 6 months and in 3 patients at 12 months

<sup>397</sup> ETH-48769 (Email 5-9-2009 addressing Pinnacle competition "...remember that de novo dyspareunia is a post op safety concern")

<sup>398</sup> ETH.MESH.00067357 (Lucente Webinar: "... the things that we all worried about tissue healing and comfort; the 2 things that, again, have plagued us all along using an implant, erosion and discomfort...")

<sup>399</sup> ETH-01121

<sup>400</sup> ETH-80645 - ETH-80651

<sup>401</sup> ETH.MESH.00067363

<sup>402</sup> Walji Deposition 3-8, p398-399, p457

<sup>403</sup> Gauld Deposition rough 4-26, p200

<sup>404</sup> Hinoul Deposition 4-5, p200

<sup>405</sup> Robinson Deposition 3-13 p299

1. Dr. Martin Weisberg
2. Dr. Piet Hinoul,
3. Dr. David Robinson,
4. Dr. Axel Arnaud,
5. Mr. Joerg Holste,
6. Dr. Aaron Kirkemo
7. Jennifer Paine
8. Catherine Beath
9. Ms. Zenobia Walji,
10. Ms. Judy Gauld
11. Dr. Aran Maree
12. Mr. Daniel Smith
13. Mr. Sean O'Bryan
14. Dr. Charlotte Owens
15. Mr. Scott Ciarrocca
16. Dr. James Hart
17. Bryan Lisa
18. Brian Kanerviko
19. Price St. Hilaire
20. Paul Parisi
21. Alex Gorsky
22. Renee Selman
23. Cliff Volpe

Each of the risks, adverse reactions, contraindications, and warnings, and the clinical consequences, should have been clearly placed and stated in the IFU so that the patients' implanting surgeon would be fully informed, and so the patient could have been informed. The following lists inadequacies in the development of the Prolift and the information provided to physicians and patients:

1. Inadequate pre-launch testing and durability studies.
2. Ineffective procedure puts women through extensive surgery with unacceptably high failure rate.
3. Dangerous procedure with incomplete IFU specifications regarding tensioning and appropriate use of trocars thereby leading to complications and failure.
4. Inadequate data to support use of Prolene Soft polypropylene mesh through the Prolift procedure in the Pelvic Floor.
5. Failure to disclose that Prolift complications are not able to be safely and effectively treated in certain patients, including the inability to safely and effectively remove the mesh when necessary, and that the complications can result in chronic, permanent debilitating pain.
6. Inaccurate and misleading claim in the IFU that the inflammatory response is slight and transient, whereas Ethicon has admitted it is chronic and in some patients severe.

7. Incomplete warnings regarding the inherent nature of the polypropylene mesh, and that a predictable increased immune response to the presence of the mesh is set off, with an increased risk of product breakdown and failure.
8. Incomplete warnings regarding the significant risks for young and sexually active women, including the failure to include a warning written by Dr. Axel Arnaud for inclusion in the initial IFU because the project leader did not want to take the time or expense to reprint the IFU, and the failure to only indicate the procedure for severe prolapse of at least stage 3 or 4, where the alternatives would not be safe or feasible, consistent with internal documents and the writings of the French inventors of the procedure. In fact, Dr. Hinoul's report in 2012 regarding the procedure indicates that the Prolift is not indicated for a patient who does not fit the criteria to be an appropriate candidate.
9. That Prolift mesh causes a lifelong risk of vaginal erosion/extrusion.
10. That Prolift mesh causes a lifelong risk of pelvic organ erosion.
11. That erosions and extrusions will be severe and incurable in some women.
12. Incomplete warning and pre-launch evaluations regarding the host's acute inflammatory response to Prolift mesh.
13. That the polypropylene mesh used to manufacture Prolift contracts in all patients, and that in some patients, this leads to complications including but not limited to nerve entrapment, pain, chronic pain, recurrence of prolapse, vaginal wall stiffness, vaginal anatomic distortion, erosion, and when this occurs the mesh cannot be safely and effectively revised or removed as necessary, including the body of the implant, and the deep arms which are virtually impossible to safely and effectively treat.
14. Incomplete warning and pre-launch evaluations regarding the risks and consequences of the host's chronic inflammatory response to Prolift polypropylene mesh.
15. That the Prolift mesh pore size is inadequate, especially in actual use, and as a result of tension and strain both during and following implantation causes fibrotic bridging/scar plating and increased contraction, and the consequences thereof.
16. That the polypropylene resins used in the meshes in Prolift have been associated with causing sarcomas at the implantation site.
17. Insufficient evaluation regarding implantation of the Prolift product into the contaminated field of the vagina.
18. Insufficient evaluation regarding Prolift product degradation/product failure due to product degradation.

19. Insufficient evaluation and warnings regarding polypropylene-related complications not seen in traditional repair.
20. Insufficient evaluation regarding and warning regarding long-term hypersensitivity to polypropylene mesh.
21. That Ethicon knew of data that the risk and consequences of vaginal scarring was greater than it disclosed in its IFU.

It is my opinion to a reasonable degree of medical probability that the Prolift is defective due to Ethicon's failure to adequately design and test the product prior to launch, failure to properly evaluate and act in response to adverse event reports and informal communications from surgeons notifying Ethicon of catastrophic complications and the failure to appropriately warn patients and health care providers of the range, severity and magnitude of the risks and complications, and consequences thereof, including, but not limited to, the following:

- a. The mesh will degrade, fragment, and elongate in some patients;
- b. The risk of chronic, refractory infections resulting from the fact that the mesh will potentiate infection (contrary to the professional education and marketing documents);
- c. The complications and consequences due to the chronic foreign body reaction due to the presence of the product;
- d. The risk of permanent vaginal or pelvic scarring as a result of the interaction with the host;
- e. The risk and consequences of vaginal extrusion;
- f. The risk of permanent vaginal shortening as a result of the product;
- g. The risk of intractable pelvic, vaginal, urethral, and systemic pain resulting from the product's interaction with the body;
- h. The need for corrective or revision surgery to revise or attempt to remove the product, which cannot be safely or effectively achieved in many instances;
- i. The severity of complications such as pelvic pain, vaginal pain, dyspareunia, overactive bladder, urinary retention and other symptoms and conditions, voiding pain that could arise as a result of implantation of the product;
- j. That the Prolift causes permanent mesh based dyspareunia;
- k. That the Prolift causes permanent pelvic pain;

- l. That the Prolift causes narrowing of the vaginal vault.
- m. The frequency of complications that result from implantation of the product;
- n. Folding, wrinkling, and bunching of the mesh inside the body, increasing the risk of contraction and other complications;
- o. Treatment of pelvic organ prolapse is no more effective than feasible available alternatives such as colporrhaphy;
- p. Treatment of pelvic organ prolapse with the Prolift procedure exposes patients to greater, and medically unreasonable risks than feasible available alternative procedures;
- q. Treatment of pelvic organ prolapse with the Prolift makes future surgical repair more difficult than the feasible available alternative procedures;
- r. The use of the Prolift procedure puts the patients at greater risk of requiring additional and morbid surgery;
- s. The removal of the products due to complications may involve multiple surgeries, significantly impair the patient's quality of life, and ultimately not successfully treat the condition;
- t. Complete removal of the products is most likely not possible and may not result in resolution of the complications, including but not limited to pain, contraction and scarring and recurrent urinary leakage and pelvic organ prolapse;
- u. Insufficient evaluation regarding and warning regarding the pullout forces of the polypropylene arms;
- v. Insufficient evaluation regarding and warning regarding the pullout forces of polypropylene arms if the mesh were to be adjusted (pulled back and forth) during the mesh tensioning portion of the procedure;
- w. Insufficient evaluation regarding and warning regarding the mesh anchoring configuration and "rolling potential" once in place in the body and muscle and fascia;
- x. Insufficient evaluation regarding, warning and IFU guidance for, polypropylene mesh placement in morbidly obese patients.



It is my opinion to a reasonable degree of medical probability that Ethicon did not fully disclose the above risks and those discussed in this report, in its IFU and to surgeons and thereby denied the patient the right to full information about her surgery. This is true despite the information being readily available and known to Ethicon about these risks, which predate the launch of the device

## **XI. Statement of Opinions**

My opinions are based on my personal knowledge, experience, and my investigation in this case. All of my opinions, and the basis of these opinions, are true and correct to the best of my knowledge and belief, including those related to scientific and medical issues, which I believe are true and correct to a reasonable degree of scientific and medical probability.

### **A. Lack of Clinical Benefit:**

1. Patients implanted with non-absorbable, transvaginal synthetic mesh for pelvic organ prolapse, including Prolift Pelvic Floor System, do not have improvement in symptomatic results over traditional, non-mesh repair.
2. Patients implanted with non-absorbable, transvaginal synthetic mesh for pelvic organ prolapse, including Prolift Pelvic Floor System, do not have improvement in or quality of life (QOL) over traditional, non-mesh repair.
3. Patients implanted with non-absorbable, transvaginal synthetic mesh for pelvic organ prolapse, including Prolift Pelvic Floor System, do not have improvement reoperation rate over traditional, non-mesh repair.
4. Because of the lack of benefit of Prolift Pelvic Floor System, the increased patient risks, complications, and added expense of these products far outweigh any stated or implied benefit.
5. There was no need for Prolift Pelvic Floor System, a non-absorbable, synthetic mesh, to be sold and marketed as a surgical treatment and procedure for pelvic organ prolapse (POP) as there were safe, effective and reasonable alternative surgical treatments available at the time this product was launched that did not needlessly endanger patients nor carry the likelihood or risk of serious injury that the Prolift product did.

### **B. Complication Rate:**

1. Synthetic transvaginal meshes for POP, including Prolift Pelvic Floor System, subject patients to needless danger through increased risks not present in traditional, non-mesh surgery for POP repair. Prolift has, therefore, caused serious and potentially permanent injuries due to complications associated with its implantation for POP repair.



2. Based on the information that was easily and readily available and abundant in the scientific literature, as well as the information known by Ethicon at the time it launched Prolift Pelvic Floor Repair Systems in 2005, a reasonably prudent and publicly responsible manufacturer should have never put this product on the market knowing that it would be permanently implanted into the pelvic region of female patients.
3. Even when surgeons used the Prolift Pelvic Floor Repair Systems as designed and marketed, it was unsafe to patients for its intended use as a method of surgical POP repair because of patient-to-patient anatomic variability and surgeon-to-surgeon variability in experience, training and technique.
4. Because non-absorbable, synthetic, polypropylene mesh such as Prolift causes an intense foreign body reaction in pelvic tissue, there is no way to safely implant these products into a woman's pelvic tissue without an increased risk of serious complications including, but not limited to, pain associated with the implant procedure (nerve and tissue damage), chronic pelvic pain associated with fibrosis and scarring, chronic infection associated with, among other things, the product's implantation into a clean/contaminated field and the intense inflammatory response to the polypropylene, chronic wound healing issues, organ erosion, vaginal extrusion/exposure, chronic pelvic pain associated with the explant procedure (nerve and tissue damage) , de novo incontinence, and significant dyspareunia (painful intercourse).

C. Data Withheld From Physicians:

1. Ethicon, the manufacturer of Prolift Pelvic Floor Repair Systems, knowingly failed to completely disclose the known risks of prolapse surgery using Prolift to physicians and patients. By withholding this information and failing to provide adequate warnings and/or instructions, Ethicon failed to act as a reasonably prudent manufacturer, and knowingly exposed patients to needless, preventable danger, harm and permanent suffering.
2. Ethicon failed to disclose the lack of benefit of POP surgery using Prolift Pelvic Floor Repair Systems to physicians and patients. By withholding this information and failing to provide adequate warnings and/or instructions, Ethicon knowingly failed to act as a reasonably prudent manufacturer and thereby exposed patients to needless danger and harm.
3. For reasons that only served to harm women and lure physicians into a false belief that Prolift Pelvic Floor Repair Systems only helped to improve sexual activity, Ethicon elected to not disclose the increased risks to sexually active women, and not to include a statement regarding the possibility of Prolift POP surgery to cause "pain with intercourse and pelvic pain", and as a result, countless women were,

and will be, permanently and needlessly forced to suffer lifelong pain and embarrassment in part due to this decision to withhold essential information.

**D. Breach of Duty by Ethicon:**

1. Ethicon breached its duty of reasonable care to implanting surgeons and to patients by marketing and selling Prolift Pelvic Floor Repair Systems as a new surgical device and procedure with insufficient evidence of either the product's or the procedure's safety, effectiveness and benefit despite knowing the risks of non-absorbable, synthetic surgical mesh for POP, including its product, Prolift.
2. Ethicon breached its duty of reasonable care to implanting surgeons and to patients by marketing and selling Prolift Pelvic Floor Repair Systems (both the product and the procedure) to surgeons and patients without proper warnings, without proper instructions for use and without sufficient evidence of its safety and efficacy, thereby exposing them to needless danger and unreasonable risk of harm.
3. Ethicon breached its duty of reasonable care to implanting surgeons and to patients by failing to disclose its knowledge of a significant increase in complications associated with Prolift through physician communications, "Dear Surgeon" letters, its sales force, sales and marketing brochures to physicians and patients and/or updates to its Instructions for Use to physicians.
4. Ethicon breached its duty of reasonable care by knowingly and falsely marketing Gynemesh PS to physicians as if the product was specially designed for treatment of POP while its intended and documented design was for abdominal wall hernia and "other fascial defects."

**XII. PREVIOUS TESTIMONY**

On November 21, 2015, my trial deposition testimony was given in *Patricia L. Hammons v. Ethicon, Inc., et al.*; All of my opinions and testimony contained within that transcript are incorporated herein by reference and attached as Exhibit "C". Additionally, as noted in Section XI below, I have given testimony and provided expert reports in numerous Ethicon transvaginal mesh cases over the past few years. All of my testimony and opinions therein are hereby incorporated by reference.

I reserve the right to modify these opinions as necessary based upon any new or additional information or data that I may obtain or with which I am presented including, without limitation, any materials that I produce in response to Ethicon's requests.

**XIII. EXHIBITS**

Exhibit "A" contains a copy of my current Curriculum Vitae.

All materials that have been available to me to consider in support of my finding and opinions are included above and listed below in Exhibit "B".

November 21, 2015 Bene Esse Transcript attached as Exhibit “C”

*Patricia L. Hammons v. Ethicon, Inc., et al.*; Philadelphia County Court of Common Pleas Case No. 0003913 – Report attached as Exhibit “D”

*Linda Gross et al. v. Gynecare, et al.*; Superior Court of New Jersey Law Division – Middlesex County Case No. MID-L-9131-08– Reports attached as Exhibit “E”

*Linda Gross et al. v. Gynecare, et al.*; Superior Court of New Jersey Law Division – Middlesex County Case No. MID-L-9131-08– Deposition attached as Exhibit “F”

*Diane Bellew v. Ethicon et al.*; United States District Court, Southern District of West Virginia Case No. 2:12-cv-22473 – Reports attached as Exhibit “G”

*Diane Bellew v. Ethicon et al.*; United States District Court, Southern District of West Virginia Case No. 2:12-cv-22473 –Deposition attached as Exhibit “H”

*Diane Bellew v. Ethicon et al.*; United States District Court, Southern District of West Virginia Case No. 2:12-cv-22473 –Trial testimony attached as Exhibit “I”

*Dale Watkins et al. vs. Ethicon, Inc. et al.*; Superior Court of New Jersey Law Division – Bergen County Case No. BER-L-13787-14 MCL – Report attached as Exhibit “J”

*Dale Watkins et al. vs. Ethicon, Inc. et al.*; Superior Court of New Jersey Law Division – Bergen County Case No. BER-L-13787-14 MCL –Deposition attached as Exhibit “K”

*Mullins et al v. Ethicon, Inc., et al.*; Southern District of West Virginia Charleston Division Case No. 2:12-cv-02952 – Report attached as Exhibit “L”

*Mullins et al v. Ethicon, Inc., et al.*; Southern District of West Virginia Charleston Division Case No. 2:12-cv-02952 – Deposition attached as Exhibit “M”

Powerpoint Presentation used during Hammons de bene esse testimony attached as Exhibit “N”

#### XIV. RECENT TESTIMONY

*Coloplast A/S v. Generical Medical Devices*; United States District Court – Western District of Washington at Tacoma Case No. C10-227BHS

*Linda Gross et al. v. Gynecare, et al.*; Superior Court of New Jersey Law Division – Middlesex County Case No. MID-L-9131-08– Report & Deposition

*Diane Bellew v. Ethicon et al.*; United States District Court, Southern District of West Virginia Case No. 2:12-cv-22473 – Report, Deposition & Trial

*Janice L. St. Cyr v. C.R. Bard, Inc. et al.*; United States District Court, Southern District of West Virginia Case No. 2:14-cv-02313

*Kathleen Stanbrough v. C.R. Bard, Inc. et al.*; United States District Court, Southern District of West Virginia Case No. 2:14-cv-06937

*Sheila Sutton v. C.R. Bard, Inc. et al.*; United States District Court, Southern District of West Virginia Case No. 2:14-cv-00105

*Pamela Ailey v Cook Medical, Inc., et al.*; United States District Court, Southern District of West Virginia Case No. 2:13-CV-20496

*Patricia L. Hammons v. Ethicon, Inc., et al.*; Philadelphia County Court of Common Pleas Case No. 0003913 – Report & De Bene Esse

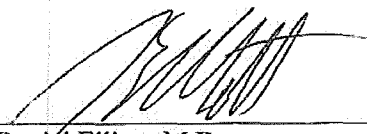
*Dale Watkins et al. vs. Ethicon, Inc. et al.*; Superior Court of New Jersey Law Division – Bergen County Case No. BER-L-13787-14 MCL – Report & Deposition

*Mullins et al v. Ethicon, Inc., et al.*; Southern District of West Virginia Charleston Division Case No. 2:12-cv-02952 – Report & Deposition

**XV. COMPENSATION**

I am compensated for investigation, study and consultation in the case at the rate of \$700.00 per hour.

DATE:

  
\_\_\_\_\_  
Daniel Elliott, M.D.

Daniel Steven Elliott, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON

IN RE: ETHICON, INC., :Master File No.  
PELVIC REPAIR SYSTEM :2:12-MD-0237  
PRODUCTS LIABILITY :  
LITIGATION :MDL No. 2327

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THIS DOCUMENT RELATES TO :JOSEPH R. GOODWIN  
THE CASES LISTED BELOW :U.S. DISTRICT JUDGE  
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Mullins, et al. V.	2:12-cv-02952
Ethicon, Inc., et al.	
Sprout, et al. V.	2:12-cv-07924
Ethicon, Inc., et al.	
Iquinto v. Ethicon, Inc., et al.	2:12-cv-09765
Daniel, et al. V.	2:13-cv-02565
Ethicon, Inc., et al.	
Dillon, et al. V.	2:13-cv-02919
Ethicon, Inc., et al.	
Webb, et al. V.	2:13-cv-04517
Ethicon, Inc., et al.	
Martinez v. Ethicon, Inc., et al.	2:13-cv-04730
McIntyre, et al. V.	2:13-cv-07283
Ethicon, Inc., et al.	
Oxley v. Ethicon, Inc., et al.	2:13-cv-10150
Atkins, et al. V.	2:13-cv-11022
Ethicon, Inc., et al.	
Garcia v. Ethicon, Inc., et al.	2:13-cv-14355
Lowe v. Ethicon, Inc., et al.	2:13-cv-14718
Dameron, et al. V.	2:13-cv-14799
Ethicon, Inc., et al.	
Vanbuskirk, et al. V.	2:13-cv-16183
Ethicon, Inc., et al.	

SEPTEMBER 26, 2015  
DANIEL STEVEN ELLIOTT, M.D.

## Daniel Steven Elliott, M.D.

Page 2	Page 4
<p>1 CAPTION CONTINUED: 2 Mullens, et al. V. 2:13-cv-16564 3 Ethicon, Inc., et al. 4 Shears, et al. V. 2:13-cv-17012 5 Ethicon, Inc., et al. 6 Javins, et al. V. 2:13-cv-18479 7 Ethicon, Inc., et al. 8 Barr, et al. V. 2:13-cv-22606 9 Ethicon, Inc., et al. 10 Lambert v. Ethicon, 2:13-cv-24393 11 Inc., et al. 12 Cook v. Ethicon, Inc. 2:13-cv-29260 13 Stevens v. Ethicon, 2:13-cv-29918 14 Inc., et al. 15 Harmon v. Ethicon, Inc. 2:13-cv-31818 16 Snodgrass v. Ethicon, 2:13-cv-31881 17 Inc., et al. 18 Miller v. Ethicon, Inc. 2:13-cv-32627 19 Matney, et al. V. 2:14-cv-09195 20 Ethicon, Inc., et al. 21 Jones, et al. V. 2:14-cv-09517 22 Ethicon, Inc., et al. 23 Humbert v. Ethicon, 2:14-cv-10640 24 Inc., et al. 25 Gillum, et al. V. 2:14-cv-12756 Ethicon, Inc., et al. Whisner, et al. V. 2:14-cv-13023 Ethicon, Inc., et al. Tomblin v. Ethicon, 2:14-cv-14664 Inc., et al. Schepleng v. Ethicon, 2:14-cv-16061 Inc., et al. Tyler, et al. V. 2:14-cv-19110 Ethicon, Inc., et al. Kelly, et al. V. 2:14-cv-22079 Ethicon, Inc., et al. Lundell v. Ethicon, 2:14-cv-24911 Inc., et al. Cheshire, et al. V. 2:14-cv-24999 Ethicon, Inc., et al. Burgoyne, et al., V. 2:14-cv-28620 Ethicon, Inc., et al. Bennett, et al., V. 2:14-cv-29624 Ethicon, Inc., et al.</p>	<p>1 APPEARANCES 2 For the Plaintiffs: 3 WAGSTAFF &amp; CARTMELL, LLP 4 4740 Grand Avenue 5 Suite 300 6 Kansas City, Missouri 64112 7 816.701.1100 8 tcartmell@wccllp.com 9 BY: THOMAS P. CARTMELL 10 11 For the Defendants: 12 13 BUTLER SNOW, LLP 14 500 Office Center Drive 15 Suite 400 16 Fort Washington, Pennsylvania 19034 17 267.513.1885 18 Burt.Snell@butlersnow.com 19 BY: NILS B. (BURT) SNELL 20 and 21 BUTLER SNOW, LLP 22 1020 Highland Colony Parkway 23 Suite 1400 24 Ridgeland, Mississippi 39157 25 601.948.5711 paul.rosenblatt@butlersnow.com BY: PAUL S. ROSENBLATT</p>
Page 3	Page 5
<p>1 DEPOSITION OF DANIEL STEVEN ELLIOTT, M.D., 2 produced, sworn and examined on behalf of the 3 Defendants, pursuant to Notice and Agreement, on 4 Saturday, the 26th day of September, 2015, between the 5 hours of 9:41 a.m. and 5:54 p.m. of that day, at the 6 law offices of Wagstaff &amp; Cartmell, LLP, 4740 Grand 7 Avenue, in the City of Kansas City, in the County of 8 Jackson, and the State of Missouri, before me, 9 NAOLA C. VAUGHN, CCR No. 1052, CRR, RPR, a Certified 10 Court Reporter, within and for the States of Missouri 11 and Kansas. 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p>1 INDEX 2 WITNESS: DANIEL STEVEN ELLIOTT, M.D. 3 Examination by Mr. Snell ..... 9, 326 4 Examination by Mr. Cartmell ..... 323 5 6 EXHIBITS 7 NUMBER DESCRIPTION PAGE 8 Exhibit 1 - Amended notice of Deposition of 9 9 Daniel Elliott, M.D. 10 Exhibit 2 - Updated publication list 11 11 Exhibit 3 - International Journal of Urology 11 12 Long-term quality of life outcomes 13 and retreatment rates after robotic 14 sacrocolpopexy 15 Exhibit 4 - The Cochrane Collaboration 54 16 Mid-urethral sling operations for 17 stress urinary incontinence in women 18 Exhibit 5 - Oxford Level of Evidence Pyramid 60 19 Exhibit 6 - International Urogynecology Journal 66 20 Long-Term (10-15 years) Follow-up 21 after Burch Colposuspension for 22 Urinary Stress Incontinence 23 Exhibit 7 - Cochrane Database Syst Rev 2015 89 24 (Dr. Elliott's copy) 25</p>



## Daniel Steven Elliott, M.D.

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1	EXHIBITS (Continued)		1	EXHIBITS (Continued)	
2	NUMBER	PAGE	2	NUMBER	PAGE
3	Exhibit 8 - American Urological Association	116	3	Exhibit 22 - In-Depth Nano-Investigation of	250
4	AUA Position Statement on the Use		4	Vaginal Mesh and Tape Fiber	
5	of Vaginal Mesh for The Surgical		5	Explants in Women	
6	Treatment of Stress Urinary		6	Exhibit 23 - FDA article on Medical Devices,	264
7	Incontinence		7	Considerations about Surgical Mesh	
8	Exhibit 9 - IUGA Position Statement on	134	8	for SUI	
9	Mid-Urethral Slings for Stress		9	Exhibit 24 - Journal of Urology, Time Dependent	289
10	Urinary Incontinence		10	Variations in Biomechanical Properties	
11	Exhibit 10 - AUGS/SUFU Position Statement on	139	11	of Cadaveric Fascia, Porcine Dermis,	
12	Mesh Midurethral Slings for Stress		12	Porcine Small Intestine submucosa,	
13	Urinary Incontinence		13	polypropylene mesh and autologous	
14	Exhibit 11 - AUGS Position Statement on	146	14	fascia in the rabbit model:	
15	Restriction of Surgical Options		15	implications for sling surgery	
16	for Pelvic Floor Disorders		16	Exhibit 25 - Urology, Time-Dependent Variations	293
17	Exhibit 12 - EAU Guidelines on Surgical	151	17	in inflammation and scar formation	
18	Treatment of Urinary Incontinence		18	of six different pubovaginal sling	
19	Exhibit 13 - EAU Guidelines on Urinary	154	19	materials in the rabbit model	
20	Incontinence		20		
21	Exhibit 14 - ICS Fact Sheets	155	21		
22	Exhibit 15 - NICE Urinary Incontinence: The	160	22		
23	management of urinary incontinence		23		
24	in women		24		
25	Exhibit 16 - Mayo Clinic web site information	171	25		
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1	EXHIBITS (Continued)		1	(Exhibit 1 marked.)	
2	NUMBER	PAGE	2	DANIEL STEVEN ELLIOTT, M.D.,	
3	Exhibit 17 - International Urogynecology Journal	178	3	a witness, being first duly sworn, testified as	
4	Long-term Results of the Tension-Free		4	follows:	
5	Vaginal Tape (TVT) Procedure for		5	EXAMINATION	
6	Surgical Treatment of Female Stress		6	BY MR. SNELL:	
7	Urinary Incontinence		7	Q. Good morning, Dr. Elliott?	
8	Exhibit 18 - Neurourology and Urodynamics	185	8	A. Good morning.	
9	Minimally Invasive Synthetic		9	Q. Can you state your full name for the	
10	Suburethral Sling Operations for		10	record, please.	
11	Stress Urinary Incontinence in Women		11	A. Daniel Steven Elliott, S-t-e-v-e-n.	
12	A Short Version Cochrane Review		12	Q. You and I know each other. I'll just	
13	Exhibit 19 - American Journal of Obstetrics and	204	13	forewarn you. I'm developing a cold and my voice	
14	Gynecology, A histologic and		14	is a little deep and cracky. And I have some	
15	immunohistochemical analysis of		15	water and I'll try to drink so it my speech is not	
16	defective vaginal healing after		16	impeded, but if you don't understand something I	
17	continence taping procedures:		17	say today, please tell me and I'll try to pose a	
18	A prospective case-controlled pilot		18	question that makes coherent sense to you.	
19	study		19	Is that okay?	
20	Exhibit 20 - Hernia Repair Sequelae	213	20	A. That is perfectly fine. Thank you.	
21	Exhibit 21 - International Urogynecologic	242	21	Q. All right. I've given you Exhibit 1,	
22	Journal, polypropylene as a		22	which is the notice for your deposition.	
23	reinforcement in pelvic surgery		23	Have you seen that document before?	
24	is not inert: Comparative		24	A. Yes.	
25	analysis of 100 explants		25	Q. All right. And what, if anything, did	

3 (Pages 6 to 9)

Daniel Steven Elliott, M.D.

Page 10	Page 12
<p>1 you do to comply with the request that you bring</p> <p>2 documents and materials that is attached to that</p> <p>3 request?</p> <p>4 A. I provided up-to-date -- well, you</p> <p>5 have already a copy of my CV. I have -- which I</p> <p>6 can provide to you. There are five new things.</p> <p>7 Just as far as what has been published, which I</p> <p>8 can provide to you there. That's a -- and then</p> <p>9 that is a copy of the manuscript, that number 5,</p> <p>10 because that just came out yesterday. So I didn't</p> <p>11 have that typed up.</p> <p>12 Q. Did you bring your file here today?</p> <p>13 A. The file? I'm sorry.</p> <p>14 Q. I guess, did you bring your expert</p> <p>15 file here today that would contain the documents</p> <p>16 and materials that you reviewed and are relying</p> <p>17 on?</p> <p>18 MR. CARTMELL: We can just -- for the</p> <p>19 record, we can get a thumb drive of everything</p> <p>20 that's on his reliance list, including that</p> <p>21 update. I just need to talk to Kuntz about that.</p> <p>22 I don't have the thumb drive with me today.</p> <p>23 Q. BY MR. SNELL: Do you have the thumb</p> <p>24 drive, Doctor?</p> <p>25 A. No. I don't have that, no. I have my</p>	<p>1 education committee. Minnesota Medical Society.</p> <p>2 Zumbro Valley Medical Society. Olmsted Community</p> <p>3 Medical Society. International Urogynecologic</p> <p>4 Society. Society of Urologic Prosthetic Surgeons.</p> <p>5 Society of Laparoendoscopic Surgeons. Minimally</p> <p>6 Invasive Robotic Association. Minnesota Urologic</p> <p>7 Society. European Association of Urology, which I</p> <p>8 am a member of, an international member, and then</p> <p>9 I'm also a member of the subsection of</p> <p>10 Genitourinary Reconstructive Surgeons, and also a</p> <p>11 member of the section of the Female Urology and</p> <p>12 Functional Urology. And again that's underneath</p> <p>13 the umbrella of the European Urology Association.</p> <p>14 International Urogynecologic Association.</p> <p>15 International Pelvic Pain Society.</p> <p>16 Q. In your role on the education</p> <p>17 committee for SUFU -- and that's the society of</p> <p>18 what?</p> <p>19 A. Good question. They changed the name.</p> <p>20 Society of Urodynamics and Female</p> <p>21 Urology is an acceptable -- but, again, they've</p> <p>22 actually moved around the words a bit there, but</p> <p>23 that's what it means.</p> <p>24 Q. Can I just call it SUFU?</p> <p>25 A. SUFU.</p>
Page 11	Page 13
<p>1 report. I do not have a copy of my reliance list.</p> <p>2 Q. Okay. So we'll mark as Exhibit 2 the</p> <p>3 five new studies that would go on your CV; is that</p> <p>4 correct?</p> <p>5 A. Correct. Those are my published</p> <p>6 studies, yes.</p> <p>7 (Exhibit 2 marked.)</p> <p>8 Q. BY MR. SNELL: We'll mark as Exhibit 3</p> <p>9 article number 5, which the lead author is Linder,</p> <p>10 L-i-n-d-e-r, then Chow, then Elliott. Long-term</p> <p>11 quality of life outcomes and retreatment rates</p> <p>12 after robotic sacrocolpopexy.</p> <p>13 (Exhibit 3 marked.)</p> <p>14 Q. BY MR. SNELL: To what professional</p> <p>15 societies do you currently belong to?</p> <p>16 A. That would be in my CV. Let me see if</p> <p>17 I have a copy of my CV. I might not. Oh, I do</p> <p>18 have one.</p> <p>19 Professional societies are going to be</p> <p>20 listed in the professional membership society on</p> <p>21 page 3 of 25. AMA, American Medical Association.</p> <p>22 American Association of Clinical Urologists.</p> <p>23 American Urologic Association. International</p> <p>24 Incontinent Society. Society of Urodynamics and</p> <p>25 Female Urology, which I am a member and on the</p>	<p>1 Q. Make it easier on the court reporter,</p> <p>2 too.</p> <p>3 A. SUFU is much better. I prefer that.</p> <p>4 Q. SUFU in all caps. Okay. What is your</p> <p>5 role -- strike that.</p> <p>6 What do you do in your role as being</p> <p>7 on the education committee for SUFU?</p> <p>8 A. It is a -- focusing on the education</p> <p>9 not only of the current residents of what we feel</p> <p>10 would be appropriate for training in female</p> <p>11 urology, urinary incontinence and prolapse, but</p> <p>12 also determining goals, objectives of education at</p> <p>13 meetings and lecture topics, things like that.</p> <p>14 Q. You've given testimony in the past;</p> <p>15 correct?</p> <p>16 A. Correct.</p> <p>17 Q. I've deposed you in the past; correct?</p> <p>18 A. Twice, I believe, yes.</p> <p>19 Q. So we can rely on your prior</p> <p>20 testimony. We don't have to ask you those</p> <p>21 questions again; correct?</p> <p>22 A. Well, with the understanding that</p> <p>23 sometimes things have changed, but, yeah, as far</p> <p>24 as data being out, those types of things.</p> <p>25 Q. Okay.</p>

4 (Pages 10 to 13)

Daniel Steven Elliott, M.D.

<p style="text-align: right;">Page 14</p> <p>1 A. That's a broad question, because those  2 are depositions over two or three days -- or two  3 days, excuse me. So I'd have to see each specific  4 question what you're talking about.  5 Q. Okay. As you sit here today, is there  6 any testimony that you gave in the Bellew or Gross  7 cases that was inaccurate or untruthful?  8 A. No. They would all been truthful and  9 accurate, but as the -- as data becomes available,  10 more research being done, as I read more internal  11 documents, certain positions may change. But  12 there's nothing dishonest or deceitful.  13 Q. In connection with the education  14 committee for SUFU, you testified that one of the  15 things that you were involved in was looking at  16 the training that residents would need in urology,  17 female urology?  18 A. Looking at the goals or where we want  19 residents to be, what criteria or surgeries,  20 volumes, types of surgeries, testing,  21 credentialing.  22 Q. Okay.  23 A. All those issues.  24 Q. And for the EAU, can I call that the  25 European Association of Urology?</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. Not really.  2 So just remind me, what section of the  3 EAU is focused on assessing the surgical options  4 for stress urinary incontinence?  5 A. That would be a function of the female  6 and functional urology.  7 Q. Are you a member of that section?  8 A. Correct. And I'm on the board of  9 that, yes.  10 Q. How long have you been on the board of  11 that section that assesses the surgical treatment  12 of stress incontinence?  13 A. Since April of 2013.  14 Q. Okay. What are your fees for your  15 work as an expert in this matter?  16 A. \$700 an hour.  17 Q. And what is your fees for testimony?  18 A. Same. \$700 an hour for everything.  19 Q. Plus travel expenses and costs?  20 A. Correct.  21 Q. How many hours have you worked on the  22 Mullins case.  23 And when I say Mullins, this is the  24 MDL design defect case.  25 A. As far as specifically on patient</p>
<p style="text-align: right;">Page 15</p> <p>1 A. EAU's easy, yeah.  2 Q. Okay. And you said you were a member  3 of the genitourinary section?  4 A. Yeah. The genitourinary  5 reconstructive. So it's reconstructive surgeons,  6 because my training is in female pelvic medicine  7 and reconstructive surgery, which are separate and  8 overlapping training.  9 Q. That would include the surgical  10 treatment of stress urinary incontinence?  11 A. That would be the other committee.  12 That would be the female urology and functional  13 urology. Reconstructive would be complications,  14 radiation damage, those types of things. Anytime  15 you hear of reconstructive, think of fixing  16 mistakes or problems.  17 Q. Are you a member of the section that  18 assesses surgical treatment options for stress  19 urinary incontinence for the EAU?  20 A. Well, the members of the female  21 functional -- we're not necessarily -- unlike the  22 SUFU, which is an education section, this is more  23 like the research that's being done. It's not  24 setting goals or guidelines by any means. I don't  25 know if that answers your questions or not.</p>	<p style="text-align: right;">Page 17</p> <p>1 Mullins, I have not reviewed her records. As far  2 as TVT and design, I guess I don't know  3 specifically -- specifically on the TVT and  4 design, it's going to be somewhat difficult to  5 ascertain exact time, because obviously the study  6 of Prolift factors in.  7 But as far as I can determine, roughly  8 60 hours have been spent as of August 31st, 2015.  9 60 hours.  10 Q. How many hours have you spent since  11 September 1st on this matter?  12 A. It's going to be difficult, because  13 there's also travel involved in there. So I don't  14 know if you want the total hours, because that's  15 not also study on things. But that'd be about  16 110 hours.  17 Q. Do you bill \$700 an hour when you  18 travel?  19 A. Correct.  20 Q. Do you issue invoices for your time  21 spent on this matter?  22 A. Correct.  23 Q. Do you send those to Ben Anderson?  24 A. Correct.  25 Q. And would those invoices be specific</p>

5 (Pages 14 to 17)

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<p style="text-align: right;">Page 18</p> <p>1 to and reference your work in the Mullins' TVT  2 design defect case?  3 A. It will be specific to Ethicon.  4 Q. Okay.  5 A. So that's why it's difficult to  6 determine exact number of hours, and that data  7 reviewed two years ago is pertinent to now. So  8 that's why it's difficult to know the total  9 number.  10 Q. You're serving as an expert against  11 other mesh manufacturers?  12 A. Yes. Mentor ObTape.  13 Q. Any others?  14 A. There was start in the Cook Surgisis  15 mesh, but last I've heard there's no action going  16 on with that.  17 I have been deposed with Avaulta.  18 But, again, nothing has happened with that in six  19 months, and I don't know where the status of those  20 are.  21 Q. Avaulta, is that a Bard product?  22 A. Correct.  23 Q. That's a prolapse product?  24 A. Prolapse product; correct.  25 Q. Okay. Does the Mayo Clinic know that</p>	<p style="text-align: right;">Page 20</p> <p>1 A. The answer to that probably would be  2 no. I could be involved in the cases, but I am  3 not the one sitting behind the robot. I am the  4 one involved directing traffic as far as the  5 dissection goes.  6 Q. Okay. What surgical options do you  7 currently use for the treatment of stress urinary  8 incontinence in your patients, if any?  9 A. Autologous pubovaginal sling,  10 cadaveric pubovaginal sling, autologous obturator  11 vagina sling, and then in the past since August of  12 2013, there's been one mesh sling. So that is a  13 change from previous testimony.  14 Q. How many autologous transobturator  15 slings do you use on average each year?  16 A. Probably it's around 80 or so. That's  17 a rough -- that's a rough number. It varies from  18 time to time. But in the past two years or --  19 yeah, two years now, I'd say 80 a year's probably  20 accurate.  21 Q. And that's the autologous  22 transobturator sling?  23 A. Correct.  24 Q. I know you published a feasibility  25 cohort study on very small sample size for the</p>
<p style="text-align: right;">Page 19</p> <p>1 you're serving as an expert for plaintiffs in the  2 mesh litigation?  3 A. No. This is all done by private time.  4 Q. I know I deposed you in two prolapse  5 cases in the past. So today I'm really focused on  6 stress urinary incontinence; all right?  7 A. Correct.  8 Q. With that said, though, let me just  9 ask you this question.  10 In the Bellew deposition you testified  11 about treatment options you used for prolapse.  12 Do you recall that, in general?  13 A. Correct.  14 Q. Have those changed as we sit here  15 today?  16 A. No.  17 Q. For Exhibit 3, the robotic  18 sacrocolpopexy cohort that you published on --  19 A. Yes.  20 Q. -- am I correct that you're not the  21 one who runs and operates the robot?  22 A. No. Dr. Chow does that.  23 Q. Okay. Are you credentialed at Mayo  24 Clinic to run the robot for sacrocolpopexy  25 procedures?</p>	<p style="text-align: right;">Page 21</p> <p>1 autologous transobturator pubovaginal sling;  2 correct?  3 A. Correct.  4 Q. That was ten patients; correct?  5 A. I believe so. It was ten patients,  6 yes.  7 Q. There's a 20 percent failure rate at a  8 mean average of four months' follow-up; correct?  9 A. Yeah. That data is now -- we're  10 looking at 60 patients with one year.  11 Q. Has that data been published?  12 A. That's in the process of being  13 gathered right now. All patients are being  14 contacted.  15 Q. How many patients are going to be in  16 that cohort, you said?  17 A. 60. It's a continuation of  18 feasibility study. Looking at safety, efficacy,  19 complications, et cetera.  20 Q. Has that data been presented anywhere  21 in abstract form or oral presentation?  22 A. Yes. I'd have to go back to the CV.  23 It was presented in February of 2015 at SUFU.  24 Again, that was the initial feasibility study.  25 Q. I think my question maybe wasn't</p>

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<p style="text-align: right;">Page 22</p> <p>1 clear.</p> <p>2 So on this updated cohort of 60</p> <p>3 patients --</p> <p>4 A. Oh, I see.</p> <p>5 Q. -- have you presented on those data</p> <p>6 anywhere?</p> <p>7 A. No. Not in the updated, no.</p> <p>8 Q. And then the small feasibility study</p> <p>9 that you did publish on, you recall the mean</p> <p>10 follow-up time was to four months?</p> <p>11 A. It was short-term, yes.</p> <p>12 Q. What's a feasibility study?</p> <p>13 A. Feasibility is a small cohort of</p> <p>14 patients that understand that they're involved in</p> <p>15 a study to determine whether or not this is a good</p> <p>16 treatment option, where we're doing quality of</p> <p>17 life assessments prior to and afterwards and</p> <p>18 following very closely, looking at complications</p> <p>19 and efficacy with 24-hour PAD tests.</p> <p>20 Q. How many cadaver slings do you use on</p> <p>21 average each year? And if that's changed year to</p> <p>22 year, you can tell me that.</p> <p>23 A. Yeah. The numbers are so -- quite</p> <p>24 variable. So it's difficult to give you a number</p> <p>25 I would say autologous slings are probably going</p>	<p style="text-align: right;">Page 24</p> <p>1 their tissue. Because mostly what I'm seeing in</p> <p>2 my practice is somebody that's been operated on</p> <p>3 multiple times. I'm not seeing usually the</p> <p>4 first-time patient. So, again, there's multiple</p> <p>5 patient variables.</p> <p>6 Q. Do you have patients for whom you</p> <p>7 offer the autologous pubovaginal sling and who</p> <p>8 decline that operation?</p> <p>9 A. I suppose that could occur, but</p> <p>10 usually those individuals are declining surgery</p> <p>11 period, not declining the autologous sling. So we</p> <p>12 have to be very careful how we're phrasing that.</p> <p>13 They are not a surgical candidate or they're</p> <p>14 choosing not to undergo surgery for their</p> <p>15 treatment. They're not saying, I do not want a</p> <p>16 autologous sling.</p> <p>17 Q. Are there patients for whom you've</p> <p>18 treated that do not want a cadaveric sling?</p> <p>19 A. I have not encountered that, no.</p> <p>20 Q. Is the autologous transobturator sling</p> <p>21 the primary -- sounds like it's the primary stress</p> <p>22 urinary incontinence surgery you're doing?</p> <p>23 A. Primary being the most common?</p> <p>24 Q. Yes, sir.</p> <p>25 A. That would be correct, sir, at this</p>
<p style="text-align: right;">Page 23</p> <p>1 to be around, let's say, 30 or so. And then</p> <p>2 cadaverics are probably going to be probably less</p> <p>3 than that. Probably 10 or so a year.</p> <p>4 Q. You do about 30 or so autologous</p> <p>5 pubovaginal slings; correct?</p> <p>6 A. About 30 a year, yes. And that will</p> <p>7 vary dramatically, yes.</p> <p>8 Q. And that's the traditional pubovaginal</p> <p>9 sling procedure that's been referenced in the</p> <p>10 literature for decades?</p> <p>11 A. Yes. With the understanding that the</p> <p>12 term "pubovaginal" is not necessarily a specific</p> <p>13 way of doing it, but in general, you are correct.</p> <p>14 Q. And that's the sling that's -- where</p> <p>15 the tissue is harvested from the patient herself;</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. And the autologous pubovaginal</p> <p>19 sling is not a medical device; is it?</p> <p>20 A. Correct. It is not.</p> <p>21 Q. Why do you only use 10 or so cadaveric</p> <p>22 slings a year?</p> <p>23 A. It's going to be dependent upon the</p> <p>24 patients, the specific patient, the criteria they</p> <p>25 have, multiple different surgeries, the quality of</p>	<p style="text-align: right;">Page 25</p> <p>1 point. But, again, we're going to analyze the</p> <p>2 data.</p> <p>3 Q. And the autologous transobturator</p> <p>4 sling is not a medical device; is that correct?</p> <p>5 A. That's correct.</p> <p>6 Q. The cadaveric sling is not a medical</p> <p>7 device; correct?</p> <p>8 A. Well, it's -- it's a device -- it's a</p> <p>9 product that is purchased from the company</p> <p>10 Coloplast. So I don't think it qualifies. It's</p> <p>11 not a man-made device.</p> <p>12 Q. It's harvested from a dead person;</p> <p>13 correct?</p> <p>14 A. Correct.</p> <p>15 Q. And the one mesh sling you used, I</p> <p>16 think you said in August of 2013?</p> <p>17 A. Correct.</p> <p>18 Q. What type of mesh sling was that?</p> <p>19 A. That was a Coloplast product, the</p> <p>20 Supris.</p> <p>21 Q. Why did you only use that Coloplast</p> <p>22 Supris on one occasion?</p> <p>23 A. That was -- I can't recall the exact</p> <p>24 patient issues with that one. There was some</p> <p>25 reason why we did not -- and that's one -- it</p>

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<p>1 wasn't in August of 2013. It's since August of</p> <p>2 2013 there's only been one. So it's a major shift</p> <p>3 in my practice. And I don't recall the reasons</p> <p>4 why we chose it, but there was a medically</p> <p>5 necessary reason, in my opinion, to do it.</p> <p>6 Q. What type of material is the Coloplast</p> <p>7 material made of?</p> <p>8 A. It is a polypropylene mesh.</p> <p>9 Q. And what route is the Coloplast Supris</p> <p>10 sling placed?</p> <p>11 A. It's a suprapubic approach.</p> <p>12 Transvaginal suprapubic.</p> <p>13 Q. Can you explain that to me? I'm</p> <p>14 familiar with retropubic and transobturator.</p> <p>15 A. Well, retropubic, all that means is</p> <p>16 behind the pubic bone. So it doesn't describe to</p> <p>17 a surgeon -- it doesn't describe -- it just</p> <p>18 describes an anatomical location. The TVT is</p> <p>19 bottom up. Supris or Sparc is top-down. That's</p> <p>20 probably -- that's the easier way to --</p> <p>21 Q. So the Colopress -- strike that.</p> <p>22 The Coloplast Supris polypropylene</p> <p>23 mesh sling uses a top-to-bottom approach?</p> <p>24 A. Correct.</p> <p>25 Q. And just so I'm clear, you've used</p>	<p>1 Q. In the past 10 years, have you used</p> <p>2 the Birch colposuspension?</p> <p>3 A. No, I have not.</p> <p>4 Q. In the past 10 years, have you used</p> <p>5 the Marshall-Marchetti-Krantz colposuspension</p> <p>6 procedure?</p> <p>7 A. No, I have not. I have not</p> <p>8 personally. I've been involved in cases -- I</p> <p>9 should take that back or strike it whatever your</p> <p>10 legal terminology is.</p> <p>11 I have been involved with GYN cases</p> <p>12 who have done the Burch. I was not the surgeon</p> <p>13 doing the Burch. I was doing something else. But</p> <p>14 I have not personally done the Burch or the MMK</p> <p>15 since fellowship, which was in '99 to 2000.</p> <p>16 Q. How many Burch procedures have you</p> <p>17 personally done in your career?</p> <p>18 A. Probably two.</p> <p>19 Q. How many MMK procedures have you</p> <p>20 personally done in your career?</p> <p>21 A. Zero.</p> <p>22 Q. The Burch colposuspension is not a</p> <p>23 medical device; correct?</p> <p>24 A. Correct.</p> <p>25 Q. Besides the Supris Coloplast sling,</p>
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<p>1 that sling on one occasion only?</p> <p>2 A. No. No. I've used that once since</p> <p>3 August of 2013. Prior to that, I probably placed</p> <p>4 1200 or so. For a while there I was doing 100 to</p> <p>5 150 slings a year. Those were synthetic slings.</p> <p>6 Those were the Coloplast, and that started in 2004</p> <p>7 or so. So whatever the math is on that. So prior</p> <p>8 to that I used another product. So what I'm</p> <p>9 saying is I've stopped using polypropylene as a</p> <p>10 first line treatment.</p> <p>11 Q. So from 2004 up to around the midpoint</p> <p>12 of 2013, August 2013 --</p> <p>13 A. Correct.</p> <p>14 Q. -- you used Coloplast polypropylene</p> <p>15 mesh slings as your primary surgical option for</p> <p>16 the treatment of stress urinary incontinence?</p> <p>17 A. That's correct. At some point in</p> <p>18 time -- I cannot recall the exact dates -- I</p> <p>19 changed from using the AMS product, because of the</p> <p>20 problems I was having with it, to the Coloplast</p> <p>21 product. Again, we have to take with a grain of</p> <p>22 salt, it was 2004, 2005, in that time frame. And</p> <p>23 then it was exclusively the Coloplast product. No</p> <p>24 other product. No other polypropylene mesh was</p> <p>25 used.</p>	<p>1 what other Coloplast slings did you use?</p> <p>2 A. The Aris. A-i -- excuse me, A-r-i-s.</p> <p>3 That is the transobturator. Same mesh, just a</p> <p>4 different route.</p> <p>5 Q. So I take it you would have began</p> <p>6 using the Coloplast Supris before the Coloplast</p> <p>7 Aris sling?</p> <p>8 A. I don't recall the sequence of how</p> <p>9 they were introduced. So it would have been about</p> <p>10 the same time, because in that time frame,</p> <p>11 transobturator route was available and suprapubic</p> <p>12 route, or top-down was available. I would think I</p> <p>13 probably started using both at the same time, if</p> <p>14 they were available. I don't recall exactly.</p> <p>15 Q. Okay. You mentioned you had some</p> <p>16 problems with AMS slings.</p> <p>17 A. Correct.</p> <p>18 Q. Were those AMS polypropylene slings?</p> <p>19 A. Correct. The Sparc, S-p-a-r-c, and</p> <p>20 the Monarc, M-o-n-a-r-c. Because of those</p> <p>21 problems, I stopped using the product.</p> <p>22 Q. Sparc is a retropubic sling?</p> <p>23 A. Correct. Top-down.</p> <p>24 Q. Top-down. And Monarc, as I understand</p> <p>25 it, is an outside and transobturator sling?</p>

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<p style="text-align: right;">Page 30</p> <p>1 A. Correct.</p> <p>2 Q. How many AMS slings do you think you</p> <p>3 placed in your career made of polypropylene?</p> <p>4 A. Yeah. I initially started -- I'll</p> <p>5 answer your question. This is complicated. I</p> <p>6 initially started using the ObTape, which was a</p> <p>7 transobturator Mentor product. Had a horrible</p> <p>8 amount of complications.</p> <p>9 So around in 2004 -- excuse me,</p> <p>10 2003 -- again, I don't recall the exact dates -- I</p> <p>11 changed over to the AMS product. And so I</p> <p>12 probably placed in a period of a year or two until</p> <p>13 the Coloplast product became available -- so you</p> <p>14 have to understand this is a guesstimate -- 100 to</p> <p>15 150 a year. So we can say 2 to 300, maybe.</p> <p>16 Q. Okay. So am I correct that the ObTape</p> <p>17 was the first synthetic sling you placed for the</p> <p>18 surgical treatment of stress urinary incontinence?</p> <p>19 A. Okay. We're going back 13, 14,</p> <p>20 15 years now. That was a transobturator route.</p> <p>21 So I was doing suprapubic prior to that. I was</p> <p>22 the first in the state of Minnesota and possibly</p> <p>23 the first in the United States to use the ObTape.</p> <p>24 At least that's what the company told me. So I</p> <p>25 was actually using the Sparc prior to that. And,</p>	<p style="text-align: right;">Page 32</p> <p>1 with the AMS Sparc and Monarc problems? Strike</p> <p>2 that. That was a bad question. I need water.</p> <p>3 When do you recall first using the</p> <p>4 ObTape?</p> <p>5 A. I'd be able to search my records and</p> <p>6 give you a pretty close to accurate date, but it</p> <p>7 would have been about in 2003, about in October or</p> <p>8 so.</p> <p>9 Q. You did a fellowship; right?</p> <p>10 A. Correct.</p> <p>11 Q. What surgeries did you learn to do to</p> <p>12 treat stress urinary incontinence during your</p> <p>13 fellowship?</p> <p>14 A. Well, that's where we did a Burch. So</p> <p>15 I'd never done Burch in residency. We only did</p> <p>16 one or two.</p> <p>17 Q. Okay.</p> <p>18 A. Where I was the surgeon or under the</p> <p>19 leadership of a staff.</p> <p>20 I had already done autologous slings.</p> <p>21 So I improved my skills. I wouldn't say I was</p> <p>22 learning something new.</p> <p>23 And then the cadaveric sling I learned</p> <p>24 there.</p> <p>25 Q. Okay.</p>
<p style="text-align: right;">Page 31</p> <p>1 again, I know it's going to be difficult. I'm not</p> <p>2 trying to be difficult. I just can't recall the</p> <p>3 exact -- so I was definitively using suprapubic</p> <p>4 prior to that time. And then transobturator came</p> <p>5 out. The Mentor at the time had the patent, two</p> <p>6 transobturators. They were the first ones to do</p> <p>7 it. So I would have used a suprapubic route</p> <p>8 first. Then transobturator with Mentor. Had</p> <p>9 problems. Then swapped over to the AMS Monarc</p> <p>10 would probably be the sequence of things.</p> <p>11 Q. What kind of problems did you have</p> <p>12 with the ObTape sling?</p> <p>13 A. You name it. It was a terrible</p> <p>14 device. It was problems of buttock abscess.</p> <p>15 Extrusion rate. Pushing out. Pain. I did it in</p> <p>16 110 patients, and we had 9 come back within a year</p> <p>17 or so with obturator fossa abscess, buttock</p> <p>18 abscess, extrusion. And then I had one patient</p> <p>19 come back in 2013. So what's that? Eight years</p> <p>20 after I implanted it with another extrusion.</p> <p>21 Q. So you had a total of 10 patients who</p> <p>22 came back with some type of complication out of</p> <p>23 110 for the ObTape?</p> <p>24 A. Correct. That I know of.</p> <p>25 Q. What type of problems did you have</p>	<p style="text-align: right;">Page 33</p> <p>1 A. Or first did there. I knew about it,</p> <p>2 but had first performed the procedure.</p> <p>3 Q. In your residency, what stress urinary</p> <p>4 incontinence surgeries did you learn about?</p> <p>5 A. Only pubovaginal, autologous</p> <p>6 pubovaginal sling.</p> <p>7 Q. Is it correct that in your fellowship</p> <p>8 you did not learn -- strike that.</p> <p>9 Is it correct in your fellowship you</p> <p>10 did not perform any synthetic slings to treat</p> <p>11 stress urinary incontinence?</p> <p>12 A. That is correct. At that point in</p> <p>13 time, only the TVT was available. My staff and</p> <p>14 residency and then my fellowship staff both did</p> <p>15 not feel it was safe; so did not do it. So my</p> <p>16 first synthetic came afterwards when the Sparc</p> <p>17 came out.</p> <p>18 Q. Is the retropubic mid-urethral sling</p> <p>19 taught in Mayo Clinic in residencies?</p> <p>20 A. It is not taught in the urology</p> <p>21 department. I cannot speak for the urogynecology</p> <p>22 department.</p> <p>23 Q. Is the retropubic mid-urethral</p> <p>24 polypropylene sling taught in fellowship at Mayo</p> <p>25 Clinic?</p>



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<p>1 A. Well, that would just be in the 2 urogynecology department. We do not have a 3 fellowship. So I don't know what they learn 4 there.</p> <p>5 Q. So circling back around to the AMS 6 sling problems that you had, what were those with 7 the Sparc and the Monarc?</p> <p>8 A. We'd have to divide it up into each 9 one, if you want. Kind of a -- because suprapubic 10 approach, the Sparc, had different complications 11 than the transobturator route.</p> <p>12 Q. Okay. Let's go with Sparc first, and 13 thanks for that clarification.</p> <p>14 A. Sparc --</p> <p>15 Q. Let me just get a good question. That 16 was a bad question on the record.</p> <p>17 Can you tell me the problems you saw 18 with the AMS Sparc device?</p> <p>19 A. Yeah. With the Sparc, it was the 20 top-down route. We had the problem with about a 21 10 percent bladder perforation rate. And then 22 also we had the problem the connector of the 23 trochar to the mesh was bulky.</p> <p>24 So per our routine, after we would 25 place our trochar we would perform a cystoscopic</p>	<p>1 A. I'm going to have to clarify that 2 statement. Actually, that's incorrect, because on 3 my CV that I turned in, we have written up the 4 largest series of bladder outlet obstruction 5 requiring urethrolysis. So in that series would 6 be some of those Sparcs that were obstructed. So 7 I don't -- I can't give you an exact number. So 8 that has been published on, yes.</p> <p>9 Q. Okay. What was the rate of bladder 10 outlet obstruction with the Sparc device in your 11 hands?</p> <p>12 A. I don't recall me personally having 13 one. The other -- my colleague had a few, about a 14 1 to 5 percent rate of obstruction.</p> <p>15 Q. Who is your colleague?</p> <p>16 A. Dr. Deborah Lightner.</p> <p>17 Q. And what was your rate of mesh 18 extrusion with the Sparc?</p> <p>19 A. I can just, off the top of my head, 20 remember a few. I did not keep accurate records 21 of the exact number of those.</p> <p>22 Q. What was the rate of pain with the 23 Sparc?</p> <p>24 A. When we closely -- you know, when we 25 asked patients to see them back, there was</p>
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<p>1 exam, and we were discovering, after we had 2 attached the mesh and pull it through, we're 3 tearing the bladder. So we developed these bad 4 tears in the bladder, when we would unequivocally 5 confirmed there was no bladder hole there to start 6 off with. So that was an unacceptable 7 complication right there.</p> <p>8 And then we were having a problem as 9 far as mesh extrusion and pain. Now, that's the 10 Sparc complications.</p> <p>11 Q. What rate of mesh extrusion did you 12 have with the Sparc device?</p> <p>13 A. It was around -- that's going to be 14 very difficult to say, because it's looking back 15 so far now.</p> <p>16 Q. Let me withdraw and ask you a question 17 that I think is easier to answer, a least it may 18 lead me to where I may want to go.</p> <p>19 Did you or anyone else ever publish on 20 these problems with the AMS Sparc device?</p> <p>21 A. We never published. We spoke about -- 22 I spoke about it. But I never had any 23 publications on it.</p> <p>24 Q. When you say you spoke about it, what 25 do you mean by that?</p>	<p>1 probably about a 5 percent risk, roughly, of 2 suprapubic pain or vaginal discomfort with it.</p> <p>3 Q. It would be routine to have the 4 patients come back following stress incontinence 5 surgery with a mid-urethral sling?</p> <p>6 A. Yes or no. It depends if we're doing 7 a study looking at something specifically. So we 8 do not have a standard protocol to follow-up with 9 them.</p> <p>10 Q. So when you put in a trans -- strike 11 that.</p> <p>12 When you put in a Sparc sling in a 13 patient, am I correct you did not have a specific 14 follow-up plan for the patient?</p> <p>15 A. We had a -- based upon efficacy only 16 at that point in time. I remember, this is back 17 in 2002 or 2003. We were -- and if the patients 18 were happy, they were continent, then we did not 19 have a scheduled follow-up for them.</p> <p>20 Q. For the autologous pubovaginal sling 21 that you would perform around that time, did you 22 have scheduled follow-ups for your patients?</p> <p>23 A. During that time frame I performed 24 very few, almost down to zero a year. There may 25 be an occasional one for a complicated</p>

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<p>1 reconstruction. So for a period of, what, seven, 2 eight years my numbers of autologous slings was 3 negligible.</p> <p>4 Q. The Aris sling is the one made by 5 Coloplast, which is a transobturator approach; 6 correct?</p> <p>7 A. Correct.</p> <p>8 Q. When you began using the Coloplast 9 Supris sling, how many randomized control trials, 10 if any, were there on that device?</p> <p>11 A. I don't recall.</p> <p>12 Q. As you sit here today, do you know if 13 there are any randomized control trials on the 14 Coloplast Supris device?</p> <p>15 A. I don't recall.</p> <p>16 Q. Do you know or do you -- you say you 17 don't recall. Do you know?</p> <p>18 A. I don't know. I have not searched the 19 literature if there is or isn't.</p> <p>20 Q. When you began using the Coloplast 21 Aris transobturator sling, were there any 22 randomized control trials that existed at that 23 time?</p> <p>24 A. Again, I don't recall back then, no.</p> <p>25 Q. As you sit here the today, do you know</p>	<p>1 There was no data. I recall trusting the company 2 that there had been data, but there apparently was 3 not.</p> <p>4 Same answer for the Sparc that I 5 believe that was already on the market when I 6 began using it.</p> <p>7 Q. But my question was for the Monarc. 8 When you began using the AMS Monarc transobturator 9 device, did you begin using it when it was 10 introduced to the market or sometime later?</p> <p>11 A. It most likely would have been 12 sometime later. Again, I don't recall the exact 13 dates.</p> <p>14 Q. When you began using the AMS Sparc 15 device, did you sit down and do a literature 16 search to ascertain what literature, if any, 17 existed on that device before using it?</p> <p>18 A. The product was brand-new to the 19 market. So there was no independent research on 20 it and definitely no long-term studies on it.</p> <p>21 Q. When you began using either the 22 Coloplast sling products, the Supris or the Aris 23 devices, did you sit down and do a literature 24 search to assess what information and data were 25 available on those products, if any, before using</p>
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<p>1 if there are any randomized control trials on the 2 Aris Coloplast sling?</p> <p>3 A. I don't know. I don't recall if there 4 are or are not.</p> <p>5 Q. When you began using the AMS Sparc 6 polypropylene sling, were there any randomized 7 control trials that existed on that device at the 8 time?</p> <p>9 A. I would have to theorize there were 10 not because it was a brand-new product on the 11 market.</p> <p>12 Q. When you began using the AMS Monarc 13 device, were there any randomized control trials 14 on that device?</p> <p>15 A. Same answer as before. I don't recall 16 if there were or were not.</p> <p>17 Q. Did you began doing the AMS Monarc 18 transobturator sling when it was introduced to the 19 market or did you wait some time?</p> <p>20 A. No. As I recall, I used the Mentor 21 ObTape first for transobturator route. Again, as 22 I was told by the company, I was the first in the 23 state of Minnesota and possibly first in the 24 United States to do transobturator because it was 25 brand-new. So that answers a lot of questions.</p>	<p>1 those products?</p> <p>2 A. I don't recall what I did at that 3 point in time, but there definitely were no 4 long-term studies because it was new to the 5 market.</p> <p>6 Q. Now, when you began doing the AMS 7 Monarc procedure, did you do a literature search 8 to see if there was any data on that particular 9 device before using it in women?</p> <p>10 A. Again, same answer as -- there was no 11 long-term studies. I don't recall if I did any 12 literature searches on it or not. I was provided 13 literature by the company, but, again, there was 14 no long-term studies.</p> <p>15 Q. What literature were you provided by 16 the company on the AMS Monarc sling?</p> <p>17 A. Their IFU and then their product 18 publicity statement, so to speak, that has the 19 blurbs on the product and how it's to be used and 20 things like that, with, you know, criteria, those 21 type things.</p> <p>22 Q. Did AMS give you any published 23 clinical studies or abstracts of clinical studies 24 at the time they gave you the IFU or the publicity 25 statement for the Monarc device?</p>

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<p>1 A. I cannot recall exactly what happened.</p> <p>2 The -- it is part of the routine of most of these</p> <p>3 reps to provide you with papers. And I don't</p> <p>4 recall that specifically with this one, no.</p> <p>5 Q. What was your mesh exposure rate, if</p> <p>6 anything, with the Coloplast Supris device?</p> <p>7 A. That I am aware of, I've had two.</p> <p>8 Q. How many mesh exposures did you have</p> <p>9 with the Coloplast Aris device?</p> <p>10 A. Oh, I'm sorry. I misspoke. Of all</p> <p>11 the -- of all the Coloplast products combined, I</p> <p>12 know of two that I've had so far. I don't know</p> <p>13 which one was which, though.</p> <p>14 Q. Okay. So it would be fair to say for</p> <p>15 the Coloplast stress incontinence polypropylene</p> <p>16 mid-urethral slings you used, those being the</p> <p>17 Supris and the Aris, you're aware of two mesh</p> <p>18 exposures?</p> <p>19 A. Correct.</p> <p>20 Q. Okay. When was the last time you used</p> <p>21 a polypropylene mid-urethral sling to treat stress</p> <p>22 urinary incontinence that utilized a top-down</p> <p>23 approach?</p> <p>24 A. That would have been the one that I</p> <p>25 did between August of 2013 to the present, and it</p>	<p>1 recall ever seeing one of my patients who was</p> <p>2 obstructed afterwards.</p> <p>3 Q. Okay. What was your rate of obturator</p> <p>4 pain you saw with the Monarc device?</p> <p>5 A. Initially was essentially 100 percent.</p> <p>6 Markedly more than the ObTape. The ObTape when</p> <p>7 you placed it, the patient initially did not</p> <p>8 complain of any obturator foramen pain. The</p> <p>9 Monarc, they complained of it significantly</p> <p>10 immediately postop. We had to give a lot more</p> <p>11 analgesic, keep patients in the hospital, those</p> <p>12 types of things. So it was unacceptable problem</p> <p>13 with the device from my perspective.</p> <p>14 Q. What was the rate of obturator pain in</p> <p>15 your Monarc patients at six months or greater?</p> <p>16 A. I don't recall. And I don't know if</p> <p>17 we ever looked at that.</p> <p>18 Q. What was the rate of dyspareunia in</p> <p>19 your Monarc patients?</p> <p>20 A. Same answer as before. I don't</p> <p>21 recall. We never did a formal study on that. So</p> <p>22 I don't know.</p> <p>23 Q. Why did you have -- strike that.</p> <p>24 Did you find that the rate of the</p> <p>25 abscesses in your use of ObTape was unacceptable?</p>
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<p>1 would have been -- I can't recall exactly. It may</p> <p>2 have been in 2013 or early 2014.</p> <p>3 Q. Have you ever placed a mid-urethral</p> <p>4 sling utilizing a retropubic approach from the</p> <p>5 bottom to the top like is employed with the TVT</p> <p>6 retropubic device?</p> <p>7 A. Never. I've seen it. But I have not</p> <p>8 performed it myself.</p> <p>9 Q. Okay. As between the -- so just so</p> <p>10 I'm clear. You've done transobturator</p> <p>11 mid-urethral polypropylene slings, and you've used</p> <p>12 suprapubic top to bottom polypropylene slings to</p> <p>13 treat stress urinary incontinence in your career?</p> <p>14 A. Correct.</p> <p>15 Q. What problems did you have with the</p> <p>16 AMS Monarc device, the transobturator device?</p> <p>17 A. Similar problems as with the</p> <p>18 suprapubic, the Sparc, in that the adaptor was</p> <p>19 very large. So as you pulled it through the</p> <p>20 obturator foramen, you had to pull very hard, tug</p> <p>21 on it, stretching the mesh, and then it'd come</p> <p>22 through forcefully. So obturator pain, patient</p> <p>23 discomfort with it. We had dyspareunia. And then</p> <p>24 you had some vaginal extrusions. I do not</p> <p>25 recall -- not that it didn't happen, I do not</p>	<p>1 A. Absolutely unacceptable.</p> <p>2 Q. Why did you have an unacceptable rate</p> <p>3 of abscesses in the ObTape?</p> <p>4 A. That was with the design of the</p> <p>5 product. It was a heavy weight, essentially zero</p> <p>6 pore mesh, polypropylene mesh that transmitted</p> <p>7 infection through the obturator foramen to the</p> <p>8 buttock region.</p> <p>9 Q. For your Coloplast polypropylene</p> <p>10 slings, what type of efficacy did you see?</p> <p>11 A. Well, there's -- again, there's the</p> <p>12 suprapubic and the obturator route. We did</p> <p>13 never -- we never looked at our rate. So I can't</p> <p>14 tell you that. Though efficacy overall was</p> <p>15 acceptable.</p> <p>16 Q. With the AMS Sparc and Monarc devices,</p> <p>17 was your efficacy with those devices acceptable?</p> <p>18 A. Yes.</p> <p>19 Q. With the Coloplast polypropylene</p> <p>20 slings, did tissue integration occur with those</p> <p>21 devices?</p> <p>22 MR. SNELL: Object to form.</p> <p>23 A. The only way to know if there was</p> <p>24 tissue integration is to do a revision surgery on</p> <p>25 them. So we never did that.</p>

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<p>1 Q. BY MR. SNELL: Did any of your</p> <p>2 patients with the Coloplast slings made of</p> <p>3 polypropylene placed at the mid-urethral come back</p> <p>4 to you with their slings falling out?</p> <p>5 A. Well, yeah, we had two that I</p> <p>6 mentioned that I know of came out. So you could</p> <p>7 say those two had poor integration, but I cannot</p> <p>8 speak to the others, because we did not have a</p> <p>9 routine follow-up scheduled for them.</p> <p>10 Q. For the two patients I thought you</p> <p>11 told me they had mesh exposures.</p> <p>12 A. They did. So that's poor tissue</p> <p>13 integration.</p> <p>14 Q. What size were those exposures?</p> <p>15 A. I don't recall. They're probably</p> <p>16 around the range of a centimeter or so. It was</p> <p>17 not just a mild exposure. These required</p> <p>18 treatment.</p> <p>19 Q. And was the tissue integrated in the</p> <p>20 area beyond the mesh exposure in those two cases?</p> <p>21 A. Again, I can't recall going back that</p> <p>22 far. I know it was not at the location of the</p> <p>23 extrusion, though.</p> <p>24 Q. What was the pore size of the</p> <p>25 Coloplast polypropylene mesh?</p>	<p>1 Q. BY MR. SNELL: What was the weight of</p> <p>2 the Coloplast slings you used for stress urinary</p> <p>3 incontinence treatment?</p> <p>4 A. 70 grams per meter squared.</p> <p>5 Q. For the AMS Sparc and Monarc slings,</p> <p>6 what was the pore size of those products?</p> <p>7 A. Well, it depends if it's coming out of</p> <p>8 the box or once you've implanted it. And so the</p> <p>9 answer is, I don't know because it was quite</p> <p>10 variable. When you placed it in the patient and</p> <p>11 then pulled on the trochars, pulled the sheath</p> <p>12 around it, it would elongate and pull and roll up.</p> <p>13 And so you'd get this rope look appearance to it,</p> <p>14 which the pore size was zero, essentially --</p> <p>15 excuse me, not zero. It was negligible.</p> <p>16 Q. How many Sparc and Monarc slings did</p> <p>17 you place in your career?</p> <p>18 A. And that's in a period of probably</p> <p>19 two, maybe three years, a rate of 100 to 150 a</p> <p>20 year.</p> <p>21 Q. And when did you first see this roping</p> <p>22 and elongation of the Sparc and Monarc slings?</p> <p>23 A. As soon as we started putting it in.</p> <p>24 Q. So you began -- just so I understand,</p> <p>25 as soon as you began seeing -- strike that.</p>
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<p>1 A. I don't know.</p> <p>2 Q. Was the Coloplast polypropylene</p> <p>3 mid-urethral sling mesh that you used mechanical</p> <p>4 cut or laser cut?</p> <p>5 A. It's actually different. It's hemmed.</p> <p>6 So the border of it looks completely different</p> <p>7 than the TVT or the Sparc. So you don't have the</p> <p>8 roping, the fraying particle loss with it or</p> <p>9 elongation. That's why I liked it over the Sparc</p> <p>10 procedure.</p> <p>11 Q. Did the Coloplast IFU for their sling</p> <p>12 products you used provide the frequency, severity,</p> <p>13 and duration of complications?</p> <p>14 A. I don't recall what the IFU said.</p> <p>15 Q. Did you read it?</p> <p>16 A. Yes, I read it.</p> <p>17 Q. As you sit here today, do you know</p> <p>18 whether those IFUs on the Coloplast mid-urethral</p> <p>19 slings ever reported frequency, severity, or</p> <p>20 duration of complications?</p> <p>21 MR. CARTMELL: Objection. Asked and</p> <p>22 answered. He just said he didn't recall.</p> <p>23 A. I don't recall, sir. It's been a long</p> <p>24 time. I know I'm required to review it, but I</p> <p>25 don't recall what they stated.</p>	<p>1 As soon as you began using the AMS</p> <p>2 polypropylene mid-urethral sling, you began seeing</p> <p>3 the roping and elongation?</p> <p>4 A. Correct.</p> <p>5 Q. Yet you continued to place 100 to 150</p> <p>6 of those a year?</p> <p>7 A. That is correct, because I didn't know</p> <p>8 the significance of it at the time.</p> <p>9 Q. Is the Sparc polypropylene sling</p> <p>10 mechanical cut or laser cut?</p> <p>11 A. I believe it is mechanical cut. In</p> <p>12 appearance it is identical to the TVT.</p> <p>13 Q. Does it have blue striping as well?</p> <p>14 A. Has a blue thread through it.</p> <p>15 Prolene -- or I believe it's Prolene suture. I'm</p> <p>16 not sure. And that was placed there not</p> <p>17 initially. That was placed afterwards to prevent</p> <p>18 the problem of it rolling, because when you'd</p> <p>19 tension it, it'd roll up.</p> <p>20 Q. And for the Monarc sling, is that</p> <p>21 mechanically cut or laser cut?</p> <p>22 A. Same answer as the Sparc. It appears</p> <p>23 to be mechanical cut. I can't speak for the cut.</p> <p>24 I've not reviewed those documents, but it appears</p> <p>25 to be mechanical cut.</p>

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<p style="text-align: right;">Page 50</p> <p>1 Q. Did you ever see particles falling off  2 of that mesh?  3 A. When you would pull on it, either the  4 Monarc or the Sparc, they're the same mesh, you  5 would pull and then you would get these little  6 tiny fibers, like just little things that you  7 could actually see on your glove. And so the  8 answer to that question is yes.  9 Q. And that did not deter you from using  10 those products?  11 A. I was unaware of the significance at  12 the time.  13 Q. Well, you knew you were implanting  14 polypropylene into the body; right?  15 A. Correct.  16 Q. And those little particles you would  17 see on your glove were made of what?  18 A. Polypropylene.  19 Q. Does the Monarc have the blue striping  20 as well?  21 A. Yeah. It has a blue Prolene -- well,  22 I assume Prolene -- suture going through end to  23 end. That's for tensioning purposes. That was  24 added later.  25 Q. Have you ever looked at the MSDS</p>	<p style="text-align: right;">Page 52</p> <p>1 A. I don't --  2 MR. CARTMELL: Let me object to the  3 form.  4 MR. SNELL: Okay.  5 MR. CARTMELL: I'm not sure what  6 you're talking about, frankly, and I'm not sure he  7 will either. So it may call for speculation.  8 A. I've reviewed a lot of documents, some  9 coming from Judge Goodwin. I don't recall the  10 nomenclature you're using.  11 Q. BY MR. SNELL: Okay. Have you seen  12 any orders by Judge Goodwin in the Mullins case?  13 A. Again, same answer as before. I  14 don't -- I've seen a lot of stuff coming from  15 Judge Goodwin with his signature or whatever on  16 it. I just don't recall the nomenclature you're  17 talking about.  18 Q. I looked through your report, and your  19 footnotes begin on page 11; correct?  20 A. That is correct.  21 Q. Actually, if you turn to page 9, you  22 have a footnote at the top, but there's no  23 citation to it.  24 A. Yeah. That is correct. That's a  25 typographical error, it looks, appears.</p>
<p style="text-align: right;">Page 51</p> <p>1 sheets that pertain to the Sparc or Monarc  2 products?  3 A. No, I have not.  4 Q. Have you ever looked at the MSDS  5 sheets that pertain to the Coloplast sling  6 products?  7 A. I have not.  8 Q. Why not?  9 A. Because I don't know how to find them.  10 Q. Am I correct; you never used the TVT  11 retropubic device?  12 A. Correct. Correct. You're right.  13 Q. And when I say TVT retropubic, I mean  14 the original, still-on-the-market-today Ethicon  15 manufactured TVT retropubic device.  16 A. Correct. The bottom up. They also  17 have a top-down. But bottom line, I have not used  18 any Ethicon product for stress urinary  19 incontinence.  20 Q. Okay. So that makes it fast. Great.  21 Before writing your report in this  22 case, did you review the order issued by the judge  23 regarding the design defect claim in Mullins, and  24 what the judge expected the parties to focus on in  25 this matter?</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. Okay.  2 A. That's my comment. Yeah, there's no  3 reason to reference that.  4 Q. Okay.  5 A. That's my comment.  6 Q. Okay. So looking at your report,  7 beginning on page 11 where you have Footnotes, the  8 majority of what you cite -- that way we can just  9 see if we can agree to this.  10 In your expert report -- strike that.  11 The majority of things that you cite  12 in your expert report in footnotes are either  13 Ethicon company documents, testimony by company  14 witnesses, or papers concerning hernia mesh or  15 prolapse.  16 Is that a fair statement?  17 MR. CARTMELL: Object to the form.  18 A. Well, the majority -- you're correct.  19 There's internal documentation. Many depositions.  20 There's the significant amount of medical  21 literature in the canine model, rabbit model,  22 human, and then there's TVT references in there,  23 too. So I can't say that -- there's a lot of  24 different references from a lot of different  25 sources.</p>

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<p>1 Q. BY MR. SNELL: Well, for the medical 2 literature, it's correct, isn't it, that you cited 3 to a lot more hernia literature than you did TVT 4 literature? 5 A. That is -- 6 MR. SNELL: Object to the form. 7 A. That is correct, because TVT is a 8 hernia mesh. 9 Q. BY MR. SNELL: And if we go to the 10 back of your report, on page 32, you cite to the 11 recent Cochrane Review by Ford, et al.? 12 A. Page 32? I'm sorry. 13 Q. Yes. Footnote 97, I see. 14 A. That is correct. 15 Q. What is a Cochrane Review? 16 A. Cochrane Review -- well, I actually 17 have a copy of it here. A Cochrane Review -- I 18 can give you the exact nomenclature that they use. 19 Yes. The Cochrane database, which is a -- I 20 believe it's government sponsored, that is in 21 charge of analyzing studies and a combination of 22 studies to hopefully be able to come up with 23 analysts -- analysis of papers and their efficacy, 24 their quality, et cetera. 25 (Exhibit 4 marked.)</p>	<p>1 large study. It's one of the bits of evidence. I 2 try to look at all evidence out there, whether it 3 be pro or con for mesh so I can get a balanced 4 opinion on this. And this is one of the 5 documents. And it's an updated one. 2015. 6 Q. Okay. Under the background, they 7 state that the mid-urethral sling operations are a 8 recognized minimally invasive surgical treatment 9 for stress urinary incontinence. 10 You see that? 11 A. That's what they state, yes. 12 Q. You would agree that the mid-urethral 13 sling is minimally invasive compared to the 14 autologous pubovaginal sling which requires 15 harvesting of tissue from the woman? 16 MR. CARTMELL: Object to the form. 17 A. I would agree, minimally invasive is 18 always a statement, has to be with qualifiers or a 19 comparison to. And I think it would be ligament 20 to say the mid-urethral sling is less invasive 21 than the autologous sling. 22 Q. BY MR. SNELL: Would you agree that 23 the mid-urethral sling, particularly the TVT 24 retropubic is less invasive than the Burch 25 colposuspension?</p>
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<p>1 Q. BY MR. SNELL: I've handed you 2 Exhibit 4. This is the intervention review of 3 mid-urethral sling operations for stress urinary 4 incontinence in women by Dr. Ford and others; 5 correct? 6 A. Well, this is the abbreviated form of 7 it, the summary. 8 Q. Right. 9 A. The real document is -- I don't know 10 how many pages, but is a very big document. 11 Q. Right. 12 A. But, yes, this is the summary, as you 13 have stated. 14 Q. And this is the same Cochrane Review 15 you cited; correct? 16 A. Correct. One by Ford, et al., in 17 2015. 18 Q. And it looks like -- the publication 19 status and date, this actually -- Cochrane Review 20 was published this summer; correct? 21 A. July. Correct. 22 Q. And if you look in the abstract -- let 23 me ask you this: Why did you cite to the Cochrane 24 Review? 25 A. Multiple different reasons. It's a</p>	<p>1 MR. CARTMELL: Same objection. 2 A. You know, possibly. But, again, 3 depends how you do it. Some people can do it with 4 a very small incision, and it's -- but it depends 5 upon -- again, it's very difficult because you 6 have to pass those trochars blind. So that's an 7 invasive thing. It's a stab wound to a patient. 8 What's the difference in making an incision and 9 putting your stitches in. But you could say, yes, 10 it is going to be less -- the TVT is going to be 11 less invasive somewhat than the Burch. 12 Q. BY MR. SNELL: Would you agree that 13 the TVT retropubic device is less invasive than 14 doing an MMK? 15 A. I think, again, same as the Burch 16 answer. The MMK requires more lateral dissection. 17 So I think that's a fair statement. 18 Q. The MMK, as I understand it, has about 19 a 2.4 percent risk of the osteopubitis. Am I 20 saying that correctly? 21 A. Correct. It should not be that high 22 of a percentage, but that is a risk of it, 23 correct. 24 Q. But you've read literature summarizing 25 that risk is 2.4 percent by authors Drews and</p>

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<p>1 others?</p> <p>2 A. I've read literature from other people</p> <p>3 saying it is less than 1 percent. But I'm not</p> <p>4 going to deny it. Yes, there is a risk of that,</p> <p>5 and that's probably one of the reasons it's not</p> <p>6 done very much.</p> <p>7 Q. And how did patients in the MMK --</p> <p>8 strike that.</p> <p>9 The MMK is a open procedure?</p> <p>10 A. Correct. I don't recall anybody doing</p> <p>11 it laparoscopically, but it's a procedure not done</p> <p>12 very often anymore.</p> <p>13 Q. How does osteopubis occur in open</p> <p>14 procedure like the MMK?</p> <p>15 A. They're thinking it's irritation to</p> <p>16 the bone with the sutures.</p> <p>17 Q. The main results of this Cochrane</p> <p>18 Review -- I want to go down a little bit.</p> <p>19 First of all, they included 81 trials;</p> <p>20 correct? I'm on this page here, Doc.</p> <p>21 A. Oh, I'm sorry. Yes.</p> <p>22 Q. That evaluated 12,113 women; correct?</p> <p>23 A. Correct.</p> <p>24 Q. The quality of most outcomes was</p> <p>25 moderate; correct?</p>	<p>1 Q. And what is the importance, if any, of</p> <p>2 Oxford Levels of Evidence?</p> <p>3 A. It is trying to quantify or</p> <p>4 demonstrate or show individuals the data that is</p> <p>5 gathered from various different studies. It does</p> <p>6 not mean that other studies are invaluable, such</p> <p>7 as case reports. But when you're trying to</p> <p>8 compare apples to oranges or different types of</p> <p>9 apples to each other, you need to compare them</p> <p>10 directly to each other. And you get arguably the</p> <p>11 better data from that type of a study.</p> <p>12 Q. Level 1 you said was an RCT?</p> <p>13 A. Correct.</p> <p>14 Q. What is level 2?</p> <p>15 A. Level 2 is a case controlled trial.</p> <p>16 Comparisons are made, but they're not randomized.</p> <p>17 Q. You pulled out a document. Could we</p> <p>18 mark that as Exhibit 5? Thank you. Oh, okay.</p> <p>19 (Exhibit 5 marked.)</p> <p>20 Q. BY MR. SNELL: I just want to look at</p> <p>21 it real quick, and then I'll give it right back to</p> <p>22 you.</p> <p>23 So where would the Cochrane Review</p> <p>24 that you cited in your expert report rate on that</p> <p>25 level of evidence pyramid?</p>
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<p>1 A. Yes. It reads, "moderate, mainly due</p> <p>2 to bias or risk of imprecision."</p> <p>3 Q. And the vast majority of these studies</p> <p>4 that were included in the Ford Cochrane Review</p> <p>5 that you cited are what are called randomized</p> <p>6 control trials; correct?</p> <p>7 A. I'm sorry. I don't understand your</p> <p>8 question. Can you -- there's misspellings on</p> <p>9 that. So can you -- I'm sorry.</p> <p>10 Q. Do you know what a randomized control</p> <p>11 trial is?</p> <p>12 A. Yes, I do.</p> <p>13 Q. Of course you do. What is a</p> <p>14 randomized control trial?</p> <p>15 A. Randomized control trial would be a</p> <p>16 level 1 trial on the Oxford education levels,</p> <p>17 where there are two different groups that are</p> <p>18 equally randomized to two separate treatment arms.</p> <p>19 And then you do the same evaluations and the same</p> <p>20 pre and postop description of patients and</p> <p>21 outcomes.</p> <p>22 Q. Okay. You mentioned the Oxford. I've</p> <p>23 heard of the Oxford Levels of Evidence.</p> <p>24 Is that what you're referring to?</p> <p>25 A. Yes. That's fine.</p>	<p>1 A. Cochrane Review is really not on it.</p> <p>2 Cochrane Review is an analysis of all the data out</p> <p>3 there. It's like a meta-analysis. Meta-analysis</p> <p>4 which are used extensively don't fall into these</p> <p>5 categories. These are smaller studies. Cochrane</p> <p>6 or meta-analysis are a combination. Like they</p> <p>7 mentioned, 81 trials that evaluated 1200 patients.</p> <p>8 Hence the reason why there'll be weaknesses or</p> <p>9 errors within those studies because they're</p> <p>10 analyzing potentially bad studies.</p> <p>11 Q. I've seen a similar evidence pyramid</p> <p>12 that has on top, above an individual randomized</p> <p>13 control trial, something called systematic reviews</p> <p>14 in meta-analyses.</p> <p>15 A. Yeah. That's why I mentioned</p> <p>16 meta-analysis. I'm not familiar with that.</p> <p>17 Q. Okay.</p> <p>18 A. But, again, as I mentioned,</p> <p>19 meta-analysis, if you take bunches of poor quality</p> <p>20 studies, you're not going to get out of that</p> <p>21 magically a good quality study. If you take dog</p> <p>22 doo and make a lot of dog doo, you still have dog</p> <p>23 doo. So you have to be careful on those types of</p> <p>24 analyses. And that's why they mention here in</p> <p>25 this Cochrane one, the quality, at most, was</p>

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<p>1 moderate, and they indicate the reason why.</p> <p>2 Q. Do you rely on meta-analyses?</p> <p>3 A. I look -- I'm a reviewer for</p> <p>4 15 different journals, and twice been awarded the</p> <p>5 best reviewer in Journal of Urology. I look at</p> <p>6 them with skepticism, because it's just -- again,</p> <p>7 as I mentioned, you have to know what goes on on</p> <p>8 each and every study to know if it's a good</p> <p>9 quality study. If you take a lot of good quality</p> <p>10 studies and put them together, that's quality.</p> <p>11 And that's why there's going to be selection, and</p> <p>12 that's why certain studies won't meet criteria.</p> <p>13 But if you just take everything and analyze it,</p> <p>14 again, it's the -- a lot of dog doo. You got a</p> <p>15 big dog doo at the end.</p> <p>16 Q. So you are aware there's a Cochrane</p> <p>17 Review for the pubovaginal sling published by</p> <p>18 Remmen.</p> <p>19 A. I don't recall that title. I'd like</p> <p>20 to see that one. I don't recall that one.</p> <p>21 Q. Let me ask you this: Do you know if</p> <p>22 there's a Cochrane Review that analyzes the</p> <p>23 pubovaginal sling?</p> <p>24 A. Yes. By Remmen.</p> <p>25 Q. So if I mispronounce a name, you can</p>	<p>1 A. There's a paper by Chaken, et al.</p> <p>2 There's another one by McGuire's group at</p> <p>3 University of Michigan, both of which had</p> <p>4 100 percent patient involvement. Some up to --</p> <p>5 involvement. Contact. So zero dropout rate</p> <p>6 except for a death, and up to 10 years of</p> <p>7 follow-up.</p> <p>8 Q. Neither one of those studies are</p> <p>9 randomized control trials; correct?</p> <p>10 A. Correct.</p> <p>11 Q. They were both retrospective cohort</p> <p>12 studies; correct?</p> <p>13 A. Yeah. The data was prospectively</p> <p>14 gathered, retrospectively reviewed.</p> <p>15 Q. And they were single center studies;</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. And Ed McGuire is the surgeon you're</p> <p>19 referring to out of Michigan; correct?</p> <p>20 A. Well, he was actually down in Houston</p> <p>21 at the time that he wrote it, but he had been in</p> <p>22 Michigan.</p> <p>23 Q. For the Burch colposuspension, are</p> <p>24 there any high quality studies that you're aware</p> <p>25 of?</p>
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<p>1 answer yes and correct me. I'm okay with that.</p> <p>2 And the quality of evidence on the</p> <p>3 pubovaginal slings by Remmen was noted to be poor;</p> <p>4 correct?</p> <p>5 A. I don't recall. I'd have to see that.</p> <p>6 I have no reason to think -- I have no reason to</p> <p>7 think that you would be wrong with that, though.</p> <p>8 I'm going to see if I have that the study. Yeah.</p> <p>9 I don't -- without knowing how to spell it, I</p> <p>10 don't know how to find it. Okay.</p> <p>11 Q. You would agree that overall the</p> <p>12 quality of studies on pubovaginal slings is poor?</p> <p>13 A. I would say the overall studies on</p> <p>14 incontinence, in general, are moderate to poor.</p> <p>15 There are very few high quality studies out there.</p> <p>16 Q. But my question is specific to the</p> <p>17 autologous pubovaginal sling. You would agree for</p> <p>18 the autologous pubovaginal sling, the quality of</p> <p>19 evidence on that procedure is poor?</p> <p>20 A. As with all the other treatments, I</p> <p>21 would agree with you, yes.</p> <p>22 Q. You mentioned there were a few high</p> <p>23 quality studies. What would those be?</p> <p>24 A. For which procedure?</p> <p>25 Q. For the autologous pubovaginal sling.</p>	<p>1 A. Yeah, there are several. I have a</p> <p>2 Langer, et al., 10 to 15 years of follow-up, Burch</p> <p>3 colposuspension, from internal -- International</p> <p>4 Urogyn Journal.</p> <p>5 Q. Do you recall what the loss to</p> <p>6 follow-up was in the Langer Burch paper?</p> <p>7 A. Of the 156 patients, 29 were admitted</p> <p>8 for not completing a 10-year follow-up. 8</p> <p>9 patients died. Can't blame them for that. 21</p> <p>10 could not be located. So actually -- so they</p> <p>11 had -- death would not factor into it. So you</p> <p>12 have 21 out of 1156 were lost to follow-up.</p> <p>13 Q. The 29 patients, what happened with</p> <p>14 them?</p> <p>15 A. Well, that's what I'm saying. 29</p> <p>16 patients were not studied. 8 died.</p> <p>17 Q. Okay.</p> <p>18 A. And 21 could not be located. So that</p> <p>19 equals a percentage of 13 percent lost to</p> <p>20 follow-up.</p> <p>21 Q. And one of the issues or problems with</p> <p>22 longer term studies is that patients can die,</p> <p>23 succumb to mortality, as you follow over a decade</p> <p>24 or more; right?</p> <p>25 A. Correct.</p>

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<p>1 Q. And that's recognized in the field as</p> <p>2 an issue when looking at randomized -- strike</p> <p>3 that.</p> <p>4 When looking at longer term studies?</p> <p>5 A. Yes and no with that. Death is looked</p> <p>6 at differently than loss -- than a true loss to</p> <p>7 follow-up. They had the 21 patients that were not</p> <p>8 able to be located. Those are important. The 8</p> <p>9 that died are still important. It's sad they</p> <p>10 died, but you look at that data differently. And</p> <p>11 statistically it's different. And that's a</p> <p>12 follow-up over 12.4 years, median follow-up.</p> <p>13 And you also asked the question about</p> <p>14 other studies. There's also Herbertsson, et al.,</p> <p>15 H-e-r-b-e-r-t-s-o-n, and then I'll spell the next</p> <p>16 one, K-j-o-e-h-e-d-e, which had 14-year follow-up,</p> <p>17 and those are specifically on Burch. So here's</p> <p>18 three studies with greater than 10 years of</p> <p>19 follow-up.</p> <p>20 Q. Can I see the paper you were looking</p> <p>21 at real quick. Can we mark this, Doctor, as an</p> <p>22 exhibit?</p> <p>23 A. Sure.</p> <p>24 MR. SNELL: What number.</p> <p>25 (Exhibit 6 marked.)</p>	<p>1 to search for that.</p> <p>2 Q. Isn't 3.9 percent rate of dyspareunia</p> <p>3 with the Burch acceptable?</p> <p>4 A. Well, I think ideally you want a zero</p> <p>5 percent dyspareunia, but you'd have to know and</p> <p>6 which this study does not have, which I would</p> <p>7 critique if I were reviewing it, is a qualifier of</p> <p>8 how bad that dyspareunia is. Is it dryness or is</p> <p>9 it a complete inability to have intercourse due to</p> <p>10 pain, but it says 3.9 percent.</p> <p>11 Q. Right. And my question is: Is that</p> <p>12 3.9 percent rate of dyspareunia with the Burch in</p> <p>13 the paper review reference acceptable?</p> <p>14 MR. CARTMELL: Object to the form.</p> <p>15 A. Again, I need to know if it was</p> <p>16 de novo or not.</p> <p>17 Q. BY MR. SNELL: So you can't answer my</p> <p>18 question?</p> <p>19 A. I would, if I can find dyspareunia in</p> <p>20 here, where they discuss it. Yeah. I don't see</p> <p>21 it. We can take a long time. I can search for</p> <p>22 it. But I would need to see how they're</p> <p>23 describing it in those things.</p> <p>24 Q. I didn't see it either.</p> <p>25 A. That is an issue with many studies.</p>
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<p>1 Q. BY MR. SNELL: Look at table 5,</p> <p>2 Doctor.</p> <p>3 A. I'm there.</p> <p>4 Q. There's a 22 percent rate of detrusor</p> <p>5 instability; correct?</p> <p>6 A. That is what they quote, yes.</p> <p>7 Q. And what is that?</p> <p>8 A. That -- I'd have to see how they</p> <p>9 define it. De novo detrusor instability was found</p> <p>10 in 17 patients. So that means, following the</p> <p>11 procedure, it caused de novo overactive bladder</p> <p>12 symptoms. So their overall rate they state is 29.</p> <p>13 But only 17 of those were caused by the procedure.</p> <p>14 Q. Okay. So about two-thirds were caused</p> <p>15 by the procedure?</p> <p>16 A. Yeah. 58 percent. So 17 out of 127</p> <p>17 had de novo. 13 percent. So when you look at</p> <p>18 graphs and tables, that's why it's difficult to be</p> <p>19 a good reviewer. You have to look at the whole</p> <p>20 big picture. Not just one graph.</p> <p>21 Q. All right. The rate of dyspareunia</p> <p>22 was 3.9 percent in this Burch study?</p> <p>23 A. That is what they quote. Again, I'd</p> <p>24 have to look at the study exactly, if that's</p> <p>25 de novo or if that's preexisting or not. I'd have</p>	<p>1 It is not included. That's why we keep saying</p> <p>2 moderate quality. No. There's only -- in the</p> <p>3 document there's only one time they mention</p> <p>4 dyspareunia, and it's in that graph. So there's</p> <p>5 no qualifiers to it.</p> <p>6 Q. But it's still a paper you pointed me</p> <p>7 to as important with regard to the Burch</p> <p>8 colposuspension; correct?</p> <p>9 A. That is correct.</p> <p>10 Q. Back to the Cochrane Review. We were</p> <p>11 looking at the Results section in the fourth</p> <p>12 paragraph. It says, "The overall rate of vaginal</p> <p>13 tape erosion/extrusion/exposure was low in both</p> <p>14 groups." It was 21 out of 1,000 for retropubic</p> <p>15 mid-urethral sling.</p> <p>16 Do you see that?</p> <p>17 A. That is what they state for the study,</p> <p>18 yes.</p> <p>19 Q. That's 2.1 percent; correct?</p> <p>20 A. That is -- that is what they state,</p> <p>21 yes.</p> <p>22 Q. The 2.1 percent would be the incidents</p> <p>23 of the mesh exposure; correct?</p> <p>24 A. Well, that's what they state with the</p> <p>25 understanding that these are short-term, moderate</p>

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<p>1 quality studies, within the hands of high-quality  2 large volume surgeons.  3 Q. So these 31 trials that they assess,  4 did all of those trials involve short-term  5 follow-up?  6 A. Well, in the situation of meshes, this  7 is an implantable permanent medical device.  8 Anything short-term -- or short of lifelong  9 follow-up is going to be inadequate, from my  10 perspective. So this is going to be short-term.  11 I doubt any of these are over 10 years, and even  12 that, in my opinion, is inadequate. But you'd  13 have to look at each individual study to find out  14 what follow-up duration was.  15 MR. SNELL: Move to strike as  16 nonresponsive.  17 Q. BY MR. SNELL: The 31 trials that were  18 assessed, is it your testimony that all of those  19 trials are short-term trials?  20 MR. CARTMELL: Object to the form.  21 A. I would have to see this complete  22 document to see each of those follow-ups to see if  23 they're adequate or not.  24 Q. BY MR. SNELL: Is there any lifelong  25 follow-up data on the Burch colposuspension,</p>	<p>1 Q. BY MR. SNELL: Let me reask the  2 question.  3 For the Burch colposuspension, are  4 there any studies that have lifelong follow-up of  5 the patients?  6 A. As I stated, the Burch is not a  7 medical device. So, no, there are no long-term  8 studies, but there don't need to be because  9 there's no permanent implantable product in the  10 patient.  11 Q. But the Burch can lead to dyspareunia,  12 just like the paper you showed me; right?  13 A. No. I disagree with that. As I  14 stated, dyspareunia was recorded, but I have no  15 idea the preoperative incidence of dyspareunia.  16 Q. So it's not important to track  17 dyspareunia with the Burch colposuspension?  18 A. No. You are spinning my words.  19 That's incorrect. I stated, in that paper there's  20 one word of dyspareunia. I don't know; did  21 10 percent have dyspareunia preop? They don't  22 mention it. Hence the quality of the paper goes  23 down.  24 So from your argument, the 10 percent  25 could have been preop, now it's down 3.9. So they</p>
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<p>1 reporting a mean follow-up of 30, 40, 50, 60 years  2 in women?  3 A. Well, as you've pointed out, it's not  4 a medical device. There doesn't need to be.  5 There can be for efficacy, but for safety and  6 complications, that's going to be all  7 perioperative. So there does not need to be.  8 You're comparing apples to oranges.  9 MR. SNELL: Move to strike as  10 nonresponsive.  11 Q. BY MR. SNELL: For the Burch  12 colposuspension, are there any lifelong follow-up  13 studies?  14 MR. CARTMELL: Objection. Asked and  15 answered. He just answered your question.  16 MR. SNELL: I don't care whether he  17 thinks it's necessary or not. I'm asking him is  18 it -- all right. Do those exist. That's a yes or  19 no or he doesn't know.  20 MR. CARTMELL: Well, he said no and  21 explained why it's not important.  22 MR. SNELL: I don't think he said no,  23 Tom. He gave me a speech.  24 MR. CARTMELL: Well, you can say no,  25 and explain again why it's not important.</p>	<p>1 did a good job.  2 Q. Do you know which way it went?  3 A. As I stated, the paper does not  4 mention that.  5 Q. Is it important to track dyspareunia  6 with the Burch colposuspension?  7 MR. CARTMELL: Object to the form.  8 A. Dyspareunia and safety of the device  9 is always important to track. It's going to be  10 different for different products. If you have a  11 permanent implantable device, you have to follow  12 it lifelong. If you have a device that's  13 absorbed, gone away, it's not as important to  14 follow.  15 Q. BY MR. SNELL: So it's not as  16 important to follow dyspareunia with the Burch  17 colposuspension; is that what you're saying?  18 A. For as long a duration.  19 Q. Is it important to follow and assess  20 dyspareunia with the Burch colposuspension out to  21 10 years?  22 A. It would be an interesting fact.  23 However, again, there's no permanent devices  24 placed in a woman. So I am more concerned about  25 the shorter term, five years, those type things.</p>

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<p>1 But even that, the suture's absorbed. It's healed 2 up. So really you can't compare TVT mesh, or any 3 mesh for that matter, and the Burch or autologous 4 fascia for that matter. 5 Q. There's scarring when you do a Burch 6 colposuspension; correct? 7 A. Yes. By six weeks it's healed up. 8 Q. And it's not important to assess 9 whether there's any painful scarring in a Burch? 10 A. Absolutely there is, but the duration 11 of the follow-up, the perioperative morbidity is 12 extremely important. But after you've done the 13 surgery, and there's healing that's happened, 14 which 98 percent happens at six weeks, one, two, 15 five-year data is important to look at. But it's 16 not as important because you don't have the 17 progressive scarring, et cetera, that you see with 18 the polypropylenes. 19 Q. How would one go about assessing the 20 lifelong -- give me a second. 21 Can I see the exhibits. 1, 2, 3. You 22 can hold on to this one. The Burch study we 23 marked a minute ago. 24 A. Oh, I'm sorry. I took that back. 25 There you go.</p>	<p>1 sling, as you described. 2 MR. SNELL: Move to strike everything 3 before "it has not been done." 4 Q. BY MR. SNELL: A registry being 5 mandatory with monitoring yearly until the death 6 of all women has never been performed for the 7 Burch colposuspension; correct? 8 A. As I've mentioned already, because 9 there's no permanent device implanted in the 10 woman, it is not necessary, but to answer your 11 question, yes. 12 MR. SNELL: Move to strike everything 13 before "to answer your question, yes" as 14 nonresponsive. 15 Q. BY MR. SNELL: For any stress urinary 16 incontinence surgery that's ever been performed 17 that you are aware of, has there ever been a 18 registry conducted that was mandatory that 19 monitored every woman yearly until her death? 20 A. Unfortunately, no. And that's why 21 we're in the situation we're in now. 22 Q. Looking back at the Cochrane Review 23 you cited in your expert report -- 24 A. Yes, sir. 25 Q. -- it says in the next paragraph, "A</p>
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<p>1 Q. Okay. That way she has it. 2 A. Okay. 3 Q. You have 5 over there? 4 A. Oh, I'm sorry. I'm taking those. 5 Q. That's okay. 6 All right. You can hold on to that 7 one. I still have some questions. 8 How would one go about conducting a 9 lifelong study on the Burch colposuspension? 10 A. A registry would be mandatory where 11 these individuals are followed. And you can't 12 have a 30 or 40 or 50 percent fallout rate. And 13 they have to be monitored on a yearly basis until 14 death. And then the true complication rate in 15 those highly experienced surgeons' hands would 16 then be known. 17 Q. And a registry being mandatory 18 monitored yearly until a woman's death has never 19 been performed for the autologous pubovaginal 20 sling; correct? 21 A. Again, for the same mentioned -- as 22 the reasons I mentioned for the Burch. There's no 23 permanent implantable device placed in that woman. 24 So the perioperative morbidity is very important, 25 but it has not been done for the pubovaginal</p>	<p>1 retropubic bottom-to-top route was more effective 2 than top-to-bottom route for subjective cure." 3 Do you see that? 4 A. That is what is stated, yes. 5 Q. And the TVT is the retropubic 6 bottom-to-top route; correct? 7 A. As far as I know, that is the only 8 bottom -- with the understanding -- let me back 9 up. 10 With the understanding that from my 11 understanding at this point right now, TVT is the 12 only one on the market bottom-up. So I don't know 13 if there's another one on the market. 14 Q. You have looked at the -- you looked 15 at the entire Cochrane Review from 4/2015 over -- 16 I think it's over 200 pages? 17 A. Very long document, yes. 18 Q. Right. Right. Right. And you saw 19 that the retropubic bottom-to-top studies were 20 studies that assessed the TVT retropubic device; 21 correct? 22 A. I don't recall that. Again, I have no 23 reason to doubt that. I'm just saying, there are 24 a lot of companies that used to make slings, 25 Boston Scientific, Bard, et cetera. I just don't</p>

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<p>1 know of another one. If that study says there's</p> <p>2 only one bottom-up and it's the TVT, I can't</p> <p>3 disagree with that. I just don't know right now.</p> <p>4 Q. You certainly know that the TVT</p> <p>5 retropubic device has been studied in more</p> <p>6 randomized control trials than any other stress</p> <p>7 urinary incontinence surgical device; correct?</p> <p>8 MR. CARTMELL: Object to the form.</p> <p>9 A. I have -- I have heard a lot of facts</p> <p>10 like that. I have never independently verified</p> <p>11 that to be true, but I don't doubt its existence.</p> <p>12 Q. BY MR. SNELL: It says the retropubic</p> <p>13 bottom-to-top route also "incurred significantly</p> <p>14 less voiding dysfunction and led to fewer bladder</p> <p>15 perforations and vaginal tape erosions"; correct?</p> <p>16 A. That is what they state, yes.</p> <p>17 Q. And those would be benefits of using a</p> <p>18 retropubic bottom-to-top route like the TVT</p> <p>19 retropubic employs as compared to a top-to-bottom</p> <p>20 route; correct?</p> <p>21 MR. CARTMELL: Object to the form.</p> <p>22 A. Well, correct except that Ethicon</p> <p>23 makes a TVT-AA, which is top-to-bottom. So based</p> <p>24 upon what they're saying here, TVT-AA would be</p> <p>25 included in the top-to-bottom. So this would be</p>	<p>1 Q. It wouldn't surprise you to learn that</p> <p>2 there were no randomized control trials on the</p> <p>3 Supris; correct?</p> <p>4 A. As I stated earlier, I was unaware of</p> <p>5 any, and hence the reason why sling data is bad.</p> <p>6 Or poor quality, let's put it that way.</p> <p>7 Q. Have you conducted an analysis of the</p> <p>8 literature regarding slings to see whether any of</p> <p>9 the other manufacturers' polypropylene slings have</p> <p>10 been subjected to more randomized control trials</p> <p>11 than the Ethicon TVT retropubic device?</p> <p>12 A. I have not done any independent</p> <p>13 research on that.</p> <p>14 Q. Have you done any PubMed searches to</p> <p>15 assess how many hundreds or thousands of studies</p> <p>16 there are on the TVT retropubic? And when I say</p> <p>17 TVT -- strike that.</p> <p>18 When I say studies, I'm not limiting</p> <p>19 it just to randomized control trials.</p> <p>20 A. I understand.</p> <p>21 Q. I mean cohort studies, studies that</p> <p>22 would comport with the level of evidence pyramid,</p> <p>23 levels 2 and 3 that you identified.</p> <p>24 MR. CARTMELL: Object to the form.</p> <p>25 A. My methodology that I use when I</p>
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<p>1 very worrisome that perhaps that TVT product</p> <p>2 employed in that fashion is actually more</p> <p>3 dangerous.</p> <p>4 Q. BY MR. SNELL: Have you ever assessed</p> <p>5 the literature on the TVT-AA device?</p> <p>6 A. There's limited data out there.</p> <p>7 Q. But have you assessed it?</p> <p>8 A. Yes, I have assessed it, and there's</p> <p>9 limited data on it.</p> <p>10 Q. And how does the voiding rates compare</p> <p>11 between the TVT retropubic and then the top-down</p> <p>12 TVT?</p> <p>13 A. The data overall with all sling</p> <p>14 products is very poor. With TVT-AA it's even</p> <p>15 worse. So I don't know. I cannot quote you a</p> <p>16 study looking at that, but I'm just saying the</p> <p>17 Cochrane analysis possibly raises the issue of a</p> <p>18 TVT-AA.</p> <p>19 Q. As you sit here today, you don't know,</p> <p>20 though whether the TVT-AA was assessed in</p> <p>21 top-to-bottom in the Cochrane Review?</p> <p>22 A. That's what I'm saying.</p> <p>23 Q. Do you know whether the Supris was</p> <p>24 assessed in this Cochrane Review?</p> <p>25 A. I don't know.</p>	<p>1 approach any of these projects is going to involve</p> <p>2 multiple different facets, but one of them is</p> <p>3 using the PubMed search engine, which is -- as far</p> <p>4 as I know, the largest search engine available,</p> <p>5 funded by the NIH. And when I search just TVT,</p> <p>6 only TVT, it comes up with about 1300 papers. But</p> <p>7 that's going to be TVT-Secur, TVT-AA, TVT -- all</p> <p>8 the TVTs.</p> <p>9 Q. BY MR. SNELL: Did you do any other</p> <p>10 search string modifiers like "tension-free vaginal</p> <p>11 tape"?</p> <p>12 A. I don't recall that --</p> <p>13 Q. TVT retropubic?</p> <p>14 A. I don't -- well, TVT is going to</p> <p>15 capture all TVTs. Tension-free vaginal tape -- I</p> <p>16 don't recall if I used that, I may have. But I</p> <p>17 searched multiple different factors looking at,</p> <p>18 you know, mesh complications associated with those</p> <p>19 things.</p> <p>20 Q. How many studies on TVT did you locate</p> <p>21 on PubMed?</p> <p>22 A. I found roughly 1300 on all TVT</p> <p>23 products, the entire product line.</p> <p>24 On just TVT retropubic or TVT classic,</p> <p>25 I can't give you a number.</p>

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<p>1 Q. Okay. How would the TVT retropubic 2 have less voiding dysfunction than a top-to-bottom 3 device like the Sparc that you used? 4 A. With my training in neurophysiology, 5 neuroanatomy and bladder dysfunction, it does not 6 make any intuitive sense why that difference would 7 be. You're passing a trochar up -- from bottom up 8 or top down, you should be -- there's -- the 9 voiding dysfunction should be identical. 10 There's going to be variables, such as 11 the mesh, the experience of the surgeon, the 12 amount of tension placed on it, the patient 13 factors in there. That's where the Cochrane 14 analysis -- we don't know; were the patients 15 morbidly obese; were they diabetics; their 16 previously existing bladder dysfunction. All 17 those factors I don't know. 18 Q. So I guess the answer to my question 19 then would be, you do not know how there would be 20 less voiding dysfunction seen with the TVT 21 retropubic as compared to a top-to-bottom device 22 like the Sparc; correct? 23 MR. CARTMELL: Object to the form. 24 Asked and answered. 25 A. Well, the statement, quote/unquote, I</p>	<p>1 incision you did when you used the Sparc? 2 A. Be 1 to 1.5 centimeters. 3 Q. And what was the other top-to-bottom 4 device you used? 5 A. The Supris. 6 Q. Supris. What was the size of the 7 vaginal incision you used with the Supris? 8 A. Same thing. 1 to 1.5 centimeters, 9 mid-urethral. 10 Q. And did you do blind passage of the 11 trochars with any of those devices? 12 A. Correct. With the Supris and the 13 Sparc, that is the identical length of blind 14 passage as with the TVT. 15 Q. And did you do blind passage with any 16 of the transobturator slings you performed? 17 A. Yes. But it's a degree -- significant 18 degree less, because you have your finger in the 19 obturator foramen. So you're passing that around 20 the obturator foramen, which is about 21 1 centimeter, but that would be blind. 22 Q. All right. You would use your finger 23 and that's known as haptic or tactile feedback; 24 correct? 25 A. I suppose. It is tactile. It's</p>
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<p>1 don't know, implies I haven't thought about it. 2 I've thought a lot about it. It does not -- I 3 cannot come up, to answer your question, with a 4 logical explanation why that's occurring. There's 5 a variable we don't know. Is it poor quality 6 studies? Patient variables? Those issues. As I 7 mentioned earlier in the previous question. 8 Q. Okay. How is it that the TVT 9 retropubic would have less vaginal tape erosions 10 than a top-to-bottom route, such as the Sparc that 11 you use? 12 A. Well, I do not use the Sparc and 13 haven't used it for 10 years or so. Or less than 14 that. Excuse me. 15 But, again, we have to include in 16 there -- unless you can show me in the Cochrane 17 study does not include the TVT-AA, that there can 18 be some of the Ethicon product in there. 19 But to answer your question, it does 20 not make logical sense, based upon the anatomical 21 approach, to have more or less or vaginal 22 extrusions. That's why there's going to be some 23 of a variable in there that we don't know in these 24 studies. 25 Q. What was the size of the vaginal</p>	<p>1 feedback. Yes, you're right. 2 Q. And that's commonly done in pelvic 3 surgery? 4 A. Pelvic surgery does a lot of surgery 5 by proprioception. Yes, by feel. 6 Q. And for the autologous transobturator 7 pubovaginal sling, part of that procedure is 8 blind; correct? 9 A. No. I disagree with that because when 10 you do a different dissection, you dissect through 11 the endopelvic fascia bilaterally. You dissect 12 along the pubic bone up to the rectus muscle. 13 Then you're able to palpate from your incision in 14 the abdomen, feel right where your finger is. So 15 you pass it through the rectus muscle and then on 16 to your finger. So there's no blind passage of 5 17 to 10 centimeters like with the Sparc or the TVT. 18 Q. But there is a blind package in that 19 procedure. It's just shorter; correct? 20 A. A significant -- well, no, there's no 21 organs that can get away. That's why there's no 22 bladder perforation, or extremely rare. In my 23 experience, I've never perforated the bladder with 24 it. Where I had a 10 percent Sparc bladder 25 perforation. And you're passing it right onto</p>

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<p>1 your finger. So there's -- you know, we can</p> <p>2 splice and say, yes, there is some blind passage,</p> <p>3 but it's right onto your finger. So you're</p> <p>4 passing it through the rectus muscle. So you're</p> <p>5 talking a centimeter.</p> <p>6 Q. In the autologous pubovaginal sling</p> <p>7 placement there's blind passage performed;</p> <p>8 correct?</p> <p>9 A. I've already answered that. That's</p> <p>10 what I just stated.</p> <p>11 Q. I'm not talking about the</p> <p>12 transobturator.</p> <p>13 A. Oh, I'm sorry. You said</p> <p>14 transobturator?</p> <p>15 Q. In the autologous pubovaginal sling</p> <p>16 that you do.</p> <p>17 A. Isn't that what I just answered</p> <p>18 already?</p> <p>19 Okay. I mean, that's the same answer</p> <p>20 as what I just stated. That your finger's right</p> <p>21 up there against the rectus muscle. The needle</p> <p>22 goes right through the rectus muscle onto your</p> <p>23 finger. So there's no blind passage, like the 5</p> <p>24 to 10 centimeters like with the TVT or the Sparc.</p> <p>25 Q. I may have got confused or maybe you</p>	<p>1 in the Langer paper; correct?</p> <p>2 A. Correct.</p> <p>3 Q. And then the Kjoehede. And I'm not</p> <p>4 sure if I'm pronouncing that correct.</p> <p>5 Do you know if that's right?</p> <p>6 A. Yeah. My Swedish is not very good.</p> <p>7 But that would be reference number 9.</p> <p>8 Q. Okay.</p> <p>9 A. Correct.</p> <p>10 Q. And do you know what percent of the</p> <p>11 women were dry in follow-up in the Kjoehede study?</p> <p>12 A. I do not. I'd have to look at the</p> <p>13 study.</p> <p>14 Q. Do you know what percentage of the</p> <p>15 women were dry in follow-up of the Herbertsson</p> <p>16 study?</p> <p>17 A. No, I'd have to look at the study.</p> <p>18 Q. And I think that's spelled can</p> <p>19 H-e-r-b-e-r-t-s-s-o-n, published in Acta, A-c-t-a,</p> <p>20 Obstet Gynecol Scand, 1993, volume 72, pages 298</p> <p>21 to 301.</p> <p>22 Correct?</p> <p>23 A. That is correct, yes.</p> <p>24 Q. And looking back at the Cochrane</p> <p>25 Review that we were discussing, under the author's</p>
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<p>1 didn't hear my earlier question right.</p> <p>2 For the autologous transobturator</p> <p>3 pubovaginal sling, that was my initial set of</p> <p>4 questions.</p> <p>5 Those involve blind passage; correct?</p> <p>6 A. That would be the same -- actually,</p> <p>7 less than with the mesh slings because we dissect</p> <p>8 deeper right underneath the muscle. So the same</p> <p>9 answer would be for the abdomen as with this.</p> <p>10 We're passing it through the obturator foramen</p> <p>11 onto your finger. So it has no chance of getting</p> <p>12 into the bladder. So if you want to define that</p> <p>13 as blind, I'll give that to you, but it's a --</p> <p>14 it's a safe passage. It's right on your finger.</p> <p>15 I'm sorry. I misunderstood your first question.</p> <p>16 MR. SNELL: It's okay. Let's take a</p> <p>17 break. We've been going for a bit. I want to use</p> <p>18 the restroom, if that's okay.</p> <p>19 MR. CARTMELL: Sure.</p> <p>20 (Recessed from 11:22 a.m. to</p> <p>21 11:41 a.m.)</p> <p>22 Q. BY MR. SNELL: Back on the record.</p> <p>23 Two of the studies you mentioned in</p> <p>24 addition to this study by Langer, L-a-n-g-e-r,</p> <p>25 were studied by Herbertsson, which is reference 8</p>	<p>1 conclusions.</p> <p>2 A. Yes, sir. Sorry.</p> <p>3 Q. You have it there?</p> <p>4 A. Yes, I do. I have both. I have my</p> <p>5 copies and then your copy.</p> <p>6 Q. Great. For the record, can we mark</p> <p>7 your copy, too, then?</p> <p>8 A. Sure.</p> <p>9 Q. Just so I can look at it at some</p> <p>10 point.</p> <p>11 (Exhibit 7 marked.)</p> <p>12 Q. BY MR. SNELL: So Exhibit 7 is your</p> <p>13 copy of this Cochrane Review by Ford, et al. we've</p> <p>14 been discussing?</p> <p>15 A. That is correct. This is the abstract</p> <p>16 off of PubMed.</p> <p>17 Q. Okay. And under the author's</p> <p>18 conclusions, it says, "mid-urethral-urethral sling</p> <p>19 operations have been the most extensively</p> <p>20 researched surgical treatment for stress urinary</p> <p>21 incontinence."</p> <p>22 You see that?</p> <p>23 A. Yes, I do.</p> <p>24 Q. And you will agree with that; correct?</p> <p>25 MR. CARTMELL: Object to the form.</p>

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<p>1 A. Again, I have no reason to doubt it. 2 But I've not done independent research on that 3 knowledge. 4 Q. BY MR. SNELL: Okay. And also it 5 says, "and have a good safety profile." 6 You would agree with that; correct? 7 MR. CARTMELL: Object to the form. 8 A. That statement needs to be taken in 9 the entirety of the paragraph, where they say 10 longer term studies are needed. But that is what 11 they state. 12 Q. BY MR. SNELL: And you agree with 13 that; correct? 14 MR. CARTMELL: Object to the form. 15 You just asked him the question. And he answered 16 it. 17 A. I agree that's what they state. And 18 then it has to be looked at in the entirety of the 19 paragraph where they say longer studies are 20 needed. 21 Q. BY MR. SNELL: And my question to you 22 is: You agree with that conclusion; correct? 23 MR. CARTMELL: Object to the form. 24 Asked and answered. 25 A. I disagree with the conclusion because</p>	<p>1 MR. SNELL: Stop it. Knock it off, 2 Tom. 3 MR. CARTMELL: No, I'm not. 4 MR. SNELL: Knock it off, Tom. 5 MR. CARTMELL: He answered your 6 question no. 7 MR. SNELL: No. 8 MR. CARTMELL: And I'm not going to 9 let you do this again. We're not going to sit in 10 here for seven hours where you ask the same 11 question five times because you don't like his 12 answer. 13 MR. SNELL: It's not about whether I 14 like his answer. 15 MR. CARTMELL: He told you he 16 disagrees with the conclusion. So move on. 17 MR. SNELL: No, he didn't. You're 18 misstating, Tom. 19 MR. CARTMELL: Tell him again. 20 MR. SNELL: You're giving speaking 21 objections on the record. 22 MR. CARTMELL: We're going to do this 23 once. 24 MR. SNELL: This is my question. 25 MR. CARTMELL: We're not going to do</p>
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<p>1 longer studies have not been done. 2 Q. BY MR. SNELL: Well, you agree that 3 mid-urethral sling operations have a good safety 4 profile with the caveat that you would like to see 5 more long-term studies done; correct? 6 MR. CARTMELL: Object to the form. 7 That misstates his testimony. And I'm not going 8 to let you do this thing where you do -- you ask 9 four different times the same question, like we 10 did the last time. 11 MR. SNELL: That's fine. 12 MR. CARTMELL: He's asked -- don't 13 answer that. You've answered it three times. 14 MR. SNELL: No, he hasn't. No, he 15 hasn't. 16 MR. CARTMELL: Yes, he has. 17 MR. SNELL: No. 18 MR. CARTMELL: He answered your 19 question. You asked if he agreed with the 20 conclusion. He said no. 21 MR. SNELL: You're wrong, Tom. He 22 said not because of the caveat that it needs more 23 long-term study. So there's my follow-up 24 question, Tom. You're playing games with me. 25 MR. CARTMELL: No, I'm not.</p>	<p>1 it again. 2 MR. SNELL: Just knock it off. This 3 is my question. You're wasting my time. This is 4 your time you're burning here, not mine. 5 Q. BY MR. SNELL: You would agree 6 mid-urethral sling have a good safety profile with 7 the caveat that you, Dr. Elliott, would like to 8 see more long-term data on those procedures; 9 correct? 10 MR. CARTMELL: Object to the form. It 11 misstates his testimony. He's already answered 12 it. 13 A. I disagree with that. 14 Q. BY MR. SNELL: Very well. Would you 15 like to see more long-term data on the autologous 16 pubovaginal sling? 17 A. Long-term studies are always going to 18 be important. However, when we're talking about 19 safety and complications, it's comparing apples to 20 oranges because there is no medical device placed 21 in those patients that's permanent. 22 Q. Can you answer it yes or no? 23 Would you like to see more long-term 24 data on the autologous pubovaginal sling? 25 MR. CARTMELL: Objection.</p>

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<p>1 Q. BY MR. SNELL: A procedure that you</p> <p>2 perform.</p> <p>3 MR. CARTMELL: Objection. Asked and</p> <p>4 answered.</p> <p>5 A. I don't necessarily know if it is</p> <p>6 actually needed. On efficacy, I would agree with</p> <p>7 you. On safety, I disagree.</p> <p>8 Q. BY MR. SNELL: This paper you gave me</p> <p>9 by Langer on the Burch says that more longer term</p> <p>10 studies are needed on the Burch because of safety;</p> <p>11 doesn't it?</p> <p>12 A. I'd have to look at the study.</p> <p>13 Q. Here. How about we look at the very</p> <p>14 last sentence. "The most significant</p> <p>15 complications are de novo detrusor instability</p> <p>16 (16.6 percent) and anatomical defects</p> <p>17 (18.9 percent), half of which appeared only 5</p> <p>18 years postoperatively, stressing the need for</p> <p>19 long-term follow-up."</p> <p>20 A. I never denied --</p> <p>21 Q. Did I read that correctly?</p> <p>22 A. I have no reason to doubt that you --</p> <p>23 that's the editorial comment. You said the</p> <p>24 author's conclusion. So you read the editorial</p> <p>25 comment. I have it highlighted there.</p>	<p>1 which can occur, but it's not an issue of safety.</p> <p>2 Q. Those authors categorized those two</p> <p>3 issues as complications; didn't they?</p> <p>4 A. They record them as complications;</p> <p>5 that's correct.</p> <p>6 Q. Back to the Cochrane Review that you</p> <p>7 cite in your report. It says that "The</p> <p>8 mid-urethral sling-urethral slings are highly</p> <p>9 effective in the short and medium term, and</p> <p>10 accruing evidence demonstrates their effectiveness</p> <p>11 in the long-term; correct?</p> <p>12 A. That's what they state, yes.</p> <p>13 Q. And you would agree with this paper</p> <p>14 you cited in your report that mid-urethral slings</p> <p>15 are highly effective in the short and medium term?</p> <p>16 MR. CARTMELL: Object to the form.</p> <p>17 A. I will never say that the -- I will</p> <p>18 not -- I agree with you as far as effectiveness.</p> <p>19 I'm never going to be challenging the</p> <p>20 effectiveness of the TVT as far as causing -- or</p> <p>21 in treating urinary incontinence. The question is</p> <p>22 always going to be at what cost.</p> <p>23 Q. BY MR. SNELL: We can agree that the</p> <p>24 TVT retropubic device is effective in the</p> <p>25 treatment of stress urinary incontinence in women?</p>
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<p>1 Q. That's not what I read. I read this.</p> <p>2 A. Okay. Now, number one, you didn't</p> <p>3 show this what you were reading so I don't know</p> <p>4 what you're reading. I go down here, and they say</p> <p>5 longer term studies.</p> <p>6 Q. I'm not reading your highlights. I'm</p> <p>7 reading what I stated.</p> <p>8 A. Okay. That's what the author states.</p> <p>9 I'm not disagreeing with that at all.</p> <p>10 Q. So there is long-term follow-up needed</p> <p>11 on the Burch to assess safety considerations;</p> <p>12 correct?</p> <p>13 MR. CARTMELL: Objection. Asked and</p> <p>14 answered.</p> <p>15 A. They never say safety. They're</p> <p>16 talking about de novo instability and anatomical</p> <p>17 defects, which anatomical defects can occur in any</p> <p>18 woman with any type of -- as long as they have a</p> <p>19 vagina there could be prolapse happening. They're</p> <p>20 not talking safety. They're talking contraction,</p> <p>21 roping, those type of things.</p> <p>22 Q. BY MR. SNELL: They're talking safety;</p> <p>23 aren't they?</p> <p>24 A. They're talking de novo instability.</p> <p>25 Okay. That's new afterwards. Anatomical defects,</p>	<p>1 MR. CARTMELL: Object to the form.</p> <p>2 A. Correct. With the caveat, at what</p> <p>3 cost.</p> <p>4 Q. BY MR. SNELL: All right. There is no</p> <p>5 stress urinary incontinence surgery that is</p> <p>6 performed in women that is more effective than the</p> <p>7 TVT retropubic; correct?</p> <p>8 MR. CARTMELL: Object to the form.</p> <p>9 A. More effective? I would have to look</p> <p>10 at all the literature out there on pubovaginal</p> <p>11 slings, including the Burch. I would say it's</p> <p>12 safe to say that the TVT, as far as efficacy, on</p> <p>13 the average, is going to be -- specifically</p> <p>14 dealing with stress urinary incontinence</p> <p>15 recurrence, is going to be as efficacious as</p> <p>16 pubovaginal and Burch, in properly trained hands.</p> <p>17 Q. BY MR. SNELL: And you've seen a</p> <p>18 conclusion very similar to that which you stated</p> <p>19 about TVT being efficacious in the treatment of</p> <p>20 stress urinary incontinence, as compared to</p> <p>21 pubovaginal slings and the Burch in the</p> <p>22 Ogah/Cochrane Review; correct?</p> <p>23 A. That's correct. Yeah.</p> <p>24 Q. That's a paper --</p> <p>25 A. They state that that -- yeah.</p>

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<p style="text-align: right;">Page 98</p> <p>1 Q. That's a paper you reviewed; correct?</p> <p>2 A. Correct. Yes.</p> <p>3 Q. You didn't cite the Ogah review in</p> <p>4 your report. Why not?</p> <p>5 A. Because I stayed the Ford one, which</p> <p>6 is an update. So I'm not going to go back to</p> <p>7 Ogah. I'm going to go to the most updated</p> <p>8 literature.</p> <p>9 Q. Ogah compared TVT to the Burch and</p> <p>10 pubovaginal slings, though?</p> <p>11 A. Okay.</p> <p>12 Q. You're aware of that; right?</p> <p>13 A. Yeah.</p> <p>14 Q. Any reason you didn't cite that</p> <p>15 comparative data by Cochrane?</p> <p>16 A. Because that's going to be a Cochrane</p> <p>17 analysis of compiling a meta-analysis, so to</p> <p>18 speak.</p> <p>19 Q. Okay.</p> <p>20 A. So using my methodology there's going</p> <p>21 to be some papers that are not going to included</p> <p>22 and others are going to be included.</p> <p>23 Q. You would agree that there's accruing</p> <p>24 evidence that -- demonstrating the efficacy of TVT</p> <p>25 retropubic in the long-term?</p>	<p style="text-align: right;">Page 100</p> <p>1 A. You'd have to show me that study.</p> <p>2 Q. Well, it's not just one study. I'm</p> <p>3 just saying from your general awareness, are you</p> <p>4 aware that for the original TVT retropubic device</p> <p>5 it has the largest volume of longer term data</p> <p>6 compared to other manufacturers' stress</p> <p>7 incontinence mid-urethral sling devices?</p> <p>8 A. I think that's probably a fair</p> <p>9 statement, yes.</p> <p>10 Q. Have you assessed the literature to</p> <p>11 ascertain how many studies with 10 years follow-up</p> <p>12 or more exist on the TVT retropubic device?</p> <p>13 A. Have I -- I'm sorry. I'm not really</p> <p>14 following your question.</p> <p>15 Have I assessed how many 10-year</p> <p>16 studies there are?</p> <p>17 Q. 10-year or more. Yes, sir.</p> <p>18 A. I looked at the literature. I</p> <p>19 reviewed it. There are studies out there. I</p> <p>20 can't give you a number, though.</p> <p>21 Q. Are you aware if studies that look at</p> <p>22 10 years duration or more specific to the TVT</p> <p>23 retropubic device assess safety issues, such as</p> <p>24 mesh exposure or dyspareunia?</p> <p>25 A. I am unaware of any study that the</p>
<p style="text-align: right;">Page 99</p> <p>1 MR. CARTMELL: Object to the form.</p> <p>2 Are you talking just efficacy?</p> <p>3 A. Well, again, I'd have to see what</p> <p>4 you're talking about as far as which papers you're</p> <p>5 referring to. But since the product has been in a</p> <p>6 long time, naturally there's going to be longer --</p> <p>7 or hopefully there's going to be longer term</p> <p>8 studies.</p> <p>9 Q. BY MR. SNELL: You're aware there are</p> <p>10 several studies that have a duration of follow-up</p> <p>11 of seven years or more with the TVT retropubic</p> <p>12 device?</p> <p>13 A. Correct.</p> <p>14 Q. I'm not talking about other</p> <p>15 manufacturers' devices.</p> <p>16 A. Yes. There are studies out there,</p> <p>17 yes.</p> <p>18 Q. Due to your -- let me back up.</p> <p>19 I don't know if I asked you this</p> <p>20 question. If I did, I apologize.</p> <p>21 You and I can agree that with regard</p> <p>22 to long-term studies following up on a</p> <p>23 mid-urethral sling that the original TVT</p> <p>24 retropubic has the most long-term data of any of</p> <p>25 those devices?</p>	<p style="text-align: right;">Page 101</p> <p>1 primary end point is on safety with the TVT.</p> <p>2 There can be a paper here and there with large</p> <p>3 amounts of follow-up -- with large amounts of lost</p> <p>4 follow-up that can refer to an erosion or</p> <p>5 exposure.</p> <p>6 Q. So you are aware that in the longer</p> <p>7 term studies with TVT they do assess safety?</p> <p>8 A. You'd have to show me those studies.</p> <p>9 I'm sorry. Because I have to look at those</p> <p>10 studies very carefully. As I mentioned, I am not</p> <p>11 aware of any with the primary end point being on</p> <p>12 safety.</p> <p>13 Q. I didn't ask you about primary end</p> <p>14 point. I asked you about assessing safety, okay?</p> <p>15 Are you aware of TVT retropubic device</p> <p>16 studies looking at it long-term that assess</p> <p>17 safety?</p> <p>18 MR. CARTMELL: Object to the form.</p> <p>19 It's vague and ambiguous as to what you mean by</p> <p>20 assess.</p> <p>21 A. There can be random --</p> <p>22 Q. BY MR. SNELL: They look on and report</p> <p>23 about whether there were mesh erosions, mesh</p> <p>24 exposures, dyspareunia, detrusor instability.</p> <p>25 Are you aware of that?</p>

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<p>1 A. They can mention -- there are studies</p> <p>2 out there that mention those various different</p> <p>3 facts. They also, you know, very rarely talk</p> <p>4 about contraction because it's not -- those</p> <p>5 patients aren't examine. They're telephone</p> <p>6 follow-ups. So, again, I'd have to look at those</p> <p>7 specific studies and we can analyze that. I'm all</p> <p>8 for that. But otherwise you're talking somewhat</p> <p>9 vague for me.</p> <p>10 Q. What studies, long-term studies on TVT</p> <p>11 are you referencing where patients were not</p> <p>12 assessed?</p> <p>13 A. Well, no. I'm saying that we'd have</p> <p>14 to pull out a study and look at it, how many of</p> <p>15 those patients came back and had a physical exam.</p> <p>16 How many of them did quality of life surveys. How</p> <p>17 many of them did global bother index. And those</p> <p>18 studies are very few. Hence, the reason why all</p> <p>19 these different societies, the AUA, for example,</p> <p>20 keep talking about moderate to low quality of</p> <p>21 studies.</p> <p>22 MR. SNELL: Move to strike as</p> <p>23 nonresponsive.</p> <p>24 Q. BY MR. SNELL: Admit your primary end</p> <p>25 point on safety.</p>	<p>1 we're comparing apples to oranges.</p> <p>2 MR. SNELL: Move to strike everything</p> <p>3 before "But to answer your question."</p> <p>4 Q. BY MR. SNELL: On the Cochrane Review</p> <p>5 that you cite in your report, the last page they</p> <p>6 say, referencing mid-urethral sling operations,</p> <p>7 are suitable for women who have -- who are having</p> <p>8 their first operation to prevent incontinence and</p> <p>9 also women who have had unsuccessful surgery</p> <p>10 previously.</p> <p>11 A. I'm sorry. I don't know where you</p> <p>12 are.</p> <p>13 Q. Back --</p> <p>14 A. You're in the Author's conclusions?</p> <p>15 Q. Background information.</p> <p>16 A. Oh, Background.</p> <p>17 Q. It's the next page, if you flip it</p> <p>18 over. Are you with me now?</p> <p>19 A. Yeah. Which paragraph are you on on</p> <p>20 Background?</p> <p>21 Q. Second paragraph.</p> <p>22 A. Second paragraph starting with, "Over</p> <p>23 the years"?</p> <p>24 Q. Second sentence.</p> <p>25 A. It starts, "Over the years"?</p>
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<p>1 How many Burch or pubovaginal sling</p> <p>2 studies are you aware of that have long-term</p> <p>3 follow-up that have a primary end point of safety?</p> <p>4 A. And you -- with -- oh, Burch or</p> <p>5 pubovaginal.</p> <p>6 I'm aware of pubovaginal because</p> <p>7 that's the procedure I'm doing. So I'm going to</p> <p>8 be more focused on that. That have 8 to 10-year</p> <p>9 follow-up where global bother index and distress</p> <p>10 inventories have been obtained.</p> <p>11 Q. Right. But how many of those had a</p> <p>12 primary end point of safety?</p> <p>13 A. It was part of the study. It was not</p> <p>14 the primary end point.</p> <p>15 Q. Just like the TVT studies; right? It</p> <p>16 was part of the study?</p> <p>17 MR. CARTMELL: Object to the form.</p> <p>18 A. Incorrect. As I've mentioned before,</p> <p>19 pubovaginal slings and Burch are not a permanent</p> <p>20 medical device that's implanted in a woman.</p> <p>21 Therefore, the bar is changed for the pubovaginal</p> <p>22 and Burch, okay.</p> <p>23 But to answer your question, I am</p> <p>24 aware -- I am not aware of any primary end point</p> <p>25 on safety with those other ones. But, again,</p>	<p>1 Q. Yes.</p> <p>2 A. And second sentence, "These operations</p> <p>3 are suitable for women...."</p> <p>4 Okay. Yes, I see that statement.</p> <p>5 Yes.</p> <p>6 Q. Would you agree that the TVT</p> <p>7 retropubic device is suitable for women who are</p> <p>8 having their first operation to prevent</p> <p>9 incontinence?</p> <p>10 A. I disagree strongly with that unless</p> <p>11 the caveat is that the woman and the physician</p> <p>12 have been fully warned of all the complications</p> <p>13 known.</p> <p>14 Q. A little bit further down, we were</p> <p>15 talking about long-term studies. And they talk</p> <p>16 about the main findings of this review.</p> <p>17 A. Under Author's conclusions?</p> <p>18 Q. Right here. We were here.</p> <p>19 A. Yeah.</p> <p>20 Q. So Main findings.</p> <p>21 A. Yes, sir.</p> <p>22 Q. So under the Main findings of the</p> <p>23 review, they stated that the trial showed over</p> <p>24 80 percent of women with stress urinary</p> <p>25 incontinence are cured or have significant</p>

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<p>1 improvement in their symptoms with either 2 operation for up to five years after surgery. 3 A. Yes, I see that statement. 4 Q. Is that an accurate statement? 5 A. That is the findings of their studies. 6 Q. Do you -- 7 A. And I have never -- and as you look at 8 my expert report, ever challenged TVT's efficacy. 9 That's not an issue with me. It's at what cost. 10 Q. At the end of that paragraph it says, 11 "The evidence that we have been able to assess 12 indicates that the positive effects persist." 13 Do you see that? 14 A. Yes, I see it. 15 Q. You did not challenge that statement 16 either; correct? 17 MR. CARTMELL: Object to the form. 18 A. The evidence that they're saying is 19 they're talking about the durability of the 20 treatment for stress urinary incontinence. As I 21 mentioned, I'm not challenging that. The question 22 is at what cost. 23 Q. BY MR. SNELL: Yeah. We can agree TVT 24 retropubic -- that that device has durability for 25 treating stress urinary incontinence in women?</p>	<p>1 also talk about main findings pertaining to 2 adverse effects; correct? 3 A. Correct. 4 Q. And it says, "Tapes passing behind the 5 pubic bone (retropubic) seem to carry a greater 6 risk of injuring the bladder"; correct? 7 A. Oh, that is correct. 8 Q. All right. And that's been reported 9 in the literature; correct? 10 A. Yes. And that's pertaining to either 11 bottom-up, top-down. 12 Q. But even for the TVT retropubic, going 13 bottom-up, it's been known that there's a risk of 14 hitting the bladder with the trochars. That's why 15 a cystoscopy is done; correct? 16 A. That is correct. And the big question 17 then becomes the ramifications of that 18 perforation, long-term erosions and those 19 things -- erosions and extrusions, yes. 20 Q. When you did your top-down passage 21 with the mid-urethral sling, I take it you also 22 did cystoscopies as well? 23 A. Always, yes. 24 Q. I know the AUA recommends cystoscopies 25 for all incontinence procedures, surgeries, as I</p>
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<p>1 A. Yes, I believe that the data, in my 2 clinical experience, would agree with that 3 statement. 4 Q. And that is a utility of the TVT 5 retropubic device; correct? 6 MR. CARTMELL: Object to the form. 7 It's vague and ambiguous with respect to what you 8 mean by "utility." 9 A. The device is designed specifically to 10 treat female stress urinary incontinence. 11 Q. BY MR. SNELL: Okay. 12 A. And so to answer your question then, 13 it has durable results in the long-term, but the 14 question is at what cost. 15 Q. Okay. The TVT retropubic device is 16 useful in treating female stress urinary 17 incontinence; correct? 18 MR. CARTMELL: Object to the form. 19 It's vague and ambiguous with respect to what you 20 mean by "useful." 21 A. It has been shown to be efficacious. 22 The question is at what cost. 23 Q. BY MR. SNELL: In this study -- strike 24 that. 25 In this Cochrane Review you cite, they</p>	<p>1 understand it. 2 Is that consistent with your 3 understanding, based upon their updated stress 4 incontinence guidelines published by Dmochowski, 5 et al.? 6 A. Dmochowski. Yeah. I don't even know 7 how to spell his name, but I know how to say it. 8 It's no problem. 9 I'd have to look at the specific 10 guidelines. For retropubic procedures, whether 11 they're top-up, bottom-down, mandatory cystoscopy. 12 Transobturator tends to be -- they say 13 they suggest it's strongly supported, but it can 14 be at the discretion of the treating physician. 15 Q. Do you do any cystoscopy when you do 16 any transobturator procedures? 17 A. I do not, no. 18 Q. You don't? 19 A. No. 20 Q. Why is that? 21 A. Because in having done 400, 500 or 22 more of those, I've never once hit the bladder, 23 because I'm dissecting right onto my finger, and I 24 bring it right out. I don't use the helical 25 trochar. Now, I've seen and taken care of a lot</p>

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<p>1 of patients with it, but I've never caused it.</p> <p>2 Q. Okay. A little further down in that</p> <p>3 paragraph in the Cochrane Review, under Adverse</p> <p>4 effects, it says, "There is moderate quality</p> <p>5 evidence that overall reported rates of</p> <p>6 tape-related complications are low, such as</p> <p>7 erosion of the tape into the vagina at about</p> <p>8 2 percent for both routes of tape insertion."</p> <p>9 Did I read that correctly?</p> <p>10 A. Yes, you did.</p> <p>11 Q. And do you agree with that?</p> <p>12 A. Disagree.</p> <p>13 Q. I didn't see in your expert report</p> <p>14 where you identify what the rate of mesh exposure</p> <p>15 was with the TVT device.</p> <p>16 A. That's because the true rate is not</p> <p>17 known.</p> <p>18 Q. I didn't see where you reported any</p> <p>19 rates of mesh exposure based on any studies for</p> <p>20 the TVT retropubic device.</p> <p>21 MR. CARTMELL: Is that a question or</p> <p>22 statement?</p> <p>23 Q. BY MR. SNELL: Am I correct, Doctor?</p> <p>24 MR. CARTMELL: We'll stipulate that</p> <p>25 that's not in there.</p>	<p>1 Q. You say these studies are done by</p> <p>2 expert high-volume surgeons.</p> <p>3 First of all, how do you define an</p> <p>4 expert high-volume surgeon?</p> <p>5 A. Well, Kuuva, et al., defined it as</p> <p>6 anybody doing -- they said the learning curve on</p> <p>7 the TVT is 15 or greater.</p> <p>8 Okay. So any -- most surgeons in the</p> <p>9 United States, based upon people sitting for the</p> <p>10 oral boards for urology, are doing 1 to 2 slings a</p> <p>11 year. Those people are not experts, but those are</p> <p>12 the people putting in the majority of slings.</p> <p>13 Okay. Now, to answer your question,</p> <p>14 how do we define an expert, it's going to be tough</p> <p>15 to say, but they're going to be doing more than</p> <p>16 that number.</p> <p>17 Q. Do you have a definition or a number</p> <p>18 in your mind, when you keep mentioning expert</p> <p>19 high-volume surgeons, what that is to you?</p> <p>20 A. It also -- because there's not a</p> <p>21 specific answer to that because it depends upon</p> <p>22 their level of training coming into the procedure</p> <p>23 or did they do a fellowship. Did they learn from</p> <p>24 an expert. Did they have Ulmsten or Nilsson come</p> <p>25 in and teach them how to do it. Those numbers are</p>
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<p>1 A. I don't believe and I don't recall</p> <p>2 stating a specific number, no.</p> <p>3 Q. BY MR. SNELL: And this Cochrane</p> <p>4 Review you cite to in your report does say that</p> <p>5 "The reported occurrence of problems with sexual</p> <p>6 intercourse including pain was low"; correct?</p> <p>7 A. That's what they state, yes.</p> <p>8 Q. And you didn't acknowledge that point</p> <p>9 in your report; did you?</p> <p>10 A. I talk about dyspareunia in there.</p> <p>11 Q. Did you acknowledge that the Cochrane</p> <p>12 Review that you cite to states that problems with</p> <p>13 sexual intercourse, including pain, were low in</p> <p>14 your report?</p> <p>15 A. I don't recall using those specific</p> <p>16 words, no.</p> <p>17 Q. Why not?</p> <p>18 A. Because, again, this is a</p> <p>19 meta-analysis of poor quality or moderate quality</p> <p>20 studies that do not focus on dyspareunia. And</p> <p>21 specifically they're short-term studies. It does</p> <p>22 not tell -- also, these are in the hands of</p> <p>23 experts, high-volume surgeons. Does not tell us</p> <p>24 the rate of the true average surgeon out there,</p> <p>25 which is known to be much higher.</p>	<p>1 going to be different than an average person who</p> <p>2 goes and has a three-hour Ethicon meeting and then</p> <p>3 goes back out in the middle of nowhere USA and</p> <p>4 puts them in. For me, I would have to say if</p> <p>5 they're not doing at least 25 or greater slings --</p> <p>6 specific sling a year, they are going to possibly</p> <p>7 be putting that patient at risk for complications.</p> <p>8 Q. Well, this study -- strike that.</p> <p>9 This Cochrane Review included 81</p> <p>10 trials. So of all the investigators in all of</p> <p>11 those 81 trials, how many of them performed at</p> <p>12 least 25 or more TVT slings in a given year?</p> <p>13 MR. CARTMELL: Do you want him to look</p> <p>14 at the underlying data and tell you that?</p> <p>15 MR. SNELL: I want him to answer my</p> <p>16 question, Tom.</p> <p>17 MR. CARTMELL: Well, but you know --</p> <p>18 A. Let's get the Cochrane analysis out</p> <p>19 and I'll look at that.</p> <p>20 MR. CARTMELL: Yeah.</p> <p>21 Q. BY MR. SNELL: Well, did you bring it</p> <p>22 here?</p> <p>23 A. No, I don't have that.</p> <p>24 Q. BY MR. SNELL: So you can't answer my</p> <p>25 question?</p>

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<p>1 A. Well, no, but you brought up the 2 issue. And so you have a question that I can't 3 answer based upon -- we have two pieces of paper, 4 81 studies. That should be roughly, what, 150 5 pages of data. I'd have to go through and look at 6 that.</p> <p>7 Q. So as you sit here today, you can't 8 answer that?</p> <p>9 A. I just answered -- I just already 10 answered that because you have not provided me 11 with the information I need.</p> <p>12 Q. I asked that you bring your file to 13 this deposition. You didn't bring it.</p> <p>14 A. Because with this study --</p> <p>15 MR. CARTMELL: Wait. For the record. 16 Let me just say this. You have been provided his 17 reliance list that has every single document on it 18 he reviewed and relied on. It has this 19 document that you only -- the full document. You 20 only provided a summary document. So if you 21 wanted to ask him questions about the full 22 document, you knew he reviewed it and relied on 23 it. You could have brought it.</p> <p>24 MR. SNELL: Here's why, Tom, I'd like 25 him to bring his file. The document he did</p>	<p>1 (Exhibit 8 marked.)</p> <p>2 Q BY MR. SNELL: So, Doctor, I've handed 3 you the American Urological Association's position 4 statement on the use of vaginal mesh for the 5 surgical treatment of stress urinary incontinence 6 from October 2013.</p> <p>7 You're aware of this; correct?</p> <p>8 A. Yes.</p> <p>9 Q. And this is the same association 10 you're a member of; correct?</p> <p>11 A. Yes.</p> <p>12 Q. And the AUA says suburethral synthetic 13 polypropylene mesh sling placement is the most 14 common surgery currently performed for stress 15 urinary incontinence"; correct?</p> <p>16 A. Yes.</p> <p>17 Q. Do you know whether that statement is 18 accurate or not?</p> <p>19 A. I don't know if it's accurate or not. 20 I have no reason to doubt its validity, though.</p> <p>21 Q. I think you're familiar with the paper 22 by Chughtai, et al., that reports on the different 23 types of stress urinary incontinence surgeries 24 performed by urologists certifying or recertifying 25 for their boards that found the mid-urethral sling</p>
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<p>1 produce has notes on every single page of the 2 studies. So whatever I could pull off the 3 internet or elsewhere, will not be the version 4 that he has that has his notes on it.</p> <p>5 MR. CARTMELL: Okay. Now, he didn't 6 have to provide you that today. He brought it 7 with him today. I mean all you -- the rules say 8 that we got to give you is the reliance list and 9 the materials. And I've told you, I'll give you 10 the materials on a -- what do you call it?</p> <p>11 MR. SNELL: Thumb drive.</p> <p>12 MR. CARTMELL: Thumb drive. But you 13 have it all. You have it all.</p> <p>14 MR. SNELL: I would like those with 15 his notes on them. Not your version of them. I 16 want Dr. Elliott's file.</p> <p>17 MR. CARTMELL: He gave you a study 18 that has his notes on it. I don't know what he 19 has that has notes on it or not, okay? But the 20 bottom line is you have the reliance materials and 21 you know every single study and paper and internal 22 document he's relied on.</p> <p>23 MR. SNELL: I don't think I know that.</p> <p>24 MR. CARTMELL: Yes, you do.</p> <p>25 MR. SNELL: All right. So move on.</p>	<p>1 to be the dominantly used procedure?</p> <p>2 A. I recall the name of that study. I 3 don't recall the data. But, again, I have no 4 reason to doubt that it's the most common. But I 5 have not done independent research to verify that.</p> <p>6 Q. Okay. The AUA statement says, 7 "Extensive data exist to support the use of 8 synthetic polypropylene mesh suburethral slings 9 for the treatment of female SUI."</p> <p>10 A. That's what they state, yes.</p> <p>11 Q. And that's an accurate statement; 12 correct?</p> <p>13 MR. CARTMELL: Object to the form.</p> <p>14 A. No. That's what they state.</p> <p>15 Q BY MR. SNELL: I know that's what they 16 state, but that is an accurate statement; correct?</p> <p>17 MR. CARTMELL: Well, is that a 18 statement by you, or are you asking him if he 19 agrees that's accurate?</p> <p>20 Q. BY MR. SNELL: I'm asking you if you 21 agree that's accurate. What I just read to you.</p> <p>22 MR. CARTMELL: Object to the form. He 23 just answered that question.</p> <p>24 MR. SNELL: He said that's what they 25 say. I know that.</p>

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<p>1 A. The document, as it says now, 2 Extensive data exist to support the use of 3 synthetic polypropylene mesh suburethral slings 4 for the treatment of SUI." 5 As we've stated before, it is 6 effective, along with pubovaginal slings and 7 Burch, to treat SUI. So I agree with that. 8 Q BY MR. SNELL: Okay. 9 A. Minimal morbidity compared to the 10 alternatives, I disagree with. So I guess, I 11 can't -- 12 Q. Okay. 13 A. It's a complicated or -- not a 14 compound sentence, whatever the -- multiple 15 aspects of t the sentence. 16 Q. What Cochrane reviews or meta-analyses 17 or randomized control trials report that the TVT 18 retropubic has -- strike that. 19 When you say you disagree that the 20 mid-urethral sling have minimal morbidity compared 21 with alternative surgeries, why do you say that? 22 A. Because there have been very few 23 randomized control trials, none which are 24 long-term, comparing head-to-head autologous 25 pubovaginal slings versus TVT. The only one I can</p>	<p>1 When you do the autologous pubovaginal 2 slings, you do general anesthesia? 3 A. That is correct. Or spinal. 4 Q. Or spinal. And that's because that's 5 a painful procedure when you have to harvest that 6 tissue from the lady; correct? 7 A. No. You don't want them moving during 8 the procedure. 9 Q. It wouldn't be painful if that was 10 under local anesthesia? 11 A. You could do it under local. It's 12 been done under local. 13 Q. Is the autologous pubovaginal sling 14 commonly done under local anesthesia? 15 A. No, I would say it is not, no. 16 Q. Why not? 17 A. Just as I mentioned, patient's going 18 to be moving. And you'd have to inject local 19 underneath the rectus fascia. It could be done. 20 But for patient comfort, most patients don't want 21 to be awake for it. You just don't do it that 22 way. 23 Q. So when the AUA says, "Advantages 24 include, and they say anesthetic need, what do 25 they mean by that?"</p>
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<p>1 think of off the top of my head is Amaro, et al., 2 from International Journal of Urology, I believe. 3 Q. Do you agree that with regard to the 4 TVT retropubic as compared to the pubovaginal 5 sling and the Burch that it has an advantage, 6 including shorter operative time? 7 A. It is shorter. Whether that's an 8 advantage or not -- surgeons get too caught up in 9 doing something in, say, 15 minutes. So it is 10 shorter. I'll give that to you. 11 Q. Okay. 12 A. Is it an advantage? That's debatable. 13 Q. Okay. Is it an advantage of the TVT 14 retropubic device that it can be done, if chosen, 15 locally, as compared to the Burch and the 16 pubovaginal slings? 17 A. Well, that's a difficult question. Is 18 that an advantage? I suppose in some highly 19 select patients. In all my years of doing this at 20 a high-volume tertiary center, I've never once had 21 to do a procedure under a local, as far as a 22 sling. I mean, so that's a theoretical potential 23 advantage. 24 Q. I'm not even going to ask you about 25 Burch.</p>	<p>1 MR. CARTMELL: Object to the form. 2 A. I suspect they're probably meaning 3 postop analgesia. 4 Q BY MR. SNELL: Is that a benefit of 5 the TVT retropubic compared to Burch and 6 pubovaginal sling? 7 A. Well, the statement they say 8 "Advantages include shorter operative time and 9 anesthetic need." 10 Q. Um-hum. 11 A. Somewhat ambiguous. I don't know if 12 they mean intraop or postop. But if you're 13 looking just at the short-term, just at the time 14 of the perioperative period, that would 15 theoretically be an advantage. But, again, it's 16 at what cost long-term. 17 Q. When you say perioperative period, 18 what are you referring to? 19 A. Meaning right before surgery, meaning 20 10 minutes before surgery, the surgery, and then 21 immediately postoperative. Like the first few 22 weeks. 23 Q. They also say, "Another advantage 24 would reduce surgical pain." 25 Do you agree that TVT retropubic has</p>

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<p>1 reduced surgical pain, and that that is an 2 advantage?</p> <p>3 A. Well, but, again, we have to go back 4 to the lack of studies. Again, I'm always aware 5 of Amaro, et al., TVT randomized versus 6 pubovaginal. In that study, hospital duration was 7 the same. And so that is debatable. But, again, 8 let's look at the short-term. I got to look at 9 long-term. As a surgeon, I got to look at 10 long-term, 10 years on down the road. So I can 11 give that to you with the caveats I mentioned.</p> <p>12 Q. So in the short-term you'd agree TVT 13 retropubic has the potential for reduced surgical 14 pain versus the Burch or the autologous 15 pubovaginal sling?</p> <p>16 MR. CARTMELL: Object to the form.</p> <p>17 A. I agree, in the immediate 18 postoperative period, let's say within the 19 first -- define that as the first six weeks of 20 surgery --</p> <p>21 Q BY MR. SNELL: Okay.</p> <p>22 A. -- especially the first week, I think 23 it's acceptable to say that the TVT would have 24 less perioperative pain than the Burch or the 25 pubovaginal sling.</p>	<p>1 RCT. So for the practice of stress urinary 2 incontinence surgery in the United States, over 3 the time period TVT retropubic device has been 4 available, would you agree that there is reduced 5 hospitalization with it compared to the autologous 6 pubovaginal sling and the Burch?</p> <p>7 A. I think there's going to be data out 8 there that supports it's a faster, quicker, and 9 less hospital stay on the average. But, again, we 10 have to look at the randomized control studies. 11 But, again, that's not an issue I'm debating. 12 It's the long-term risks that I'm talking about.</p> <p>13 Q. It says another advantage is reduced 14 voiding dysfunction.</p> <p>15 Do you believe that's a potential 16 advantage for the TVT retropubic versus the 17 autologous pubovaginal slings?</p> <p>18 MR. CARTMELL: Object to the form. 19 It's vague and ambiguous with respect to what you 20 mean by voiding dysfunction.</p> <p>21 A. Well, no, I disagree with that. I'd 22 have to say show me the -- that one very 23 specifically, you're going to need level 1 data to 24 support that. You cannot take cohort studies and 25 compare cohort to cohort. And so that one is</p>
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<p>1 Q. When you do your pubovaginal slings, 2 do you give your patients pain medicines?</p> <p>3 A. Yes.</p> <p>4 Q. Why?</p> <p>5 A. To reduce the perioperative pain.</p> <p>6 Q. How long do you give them pain 7 medications?</p> <p>8 A. We give them 10 to 15 tablets of a 9 narcotic, and they take it if they need it. They 10 stop it if they don't. So I don't know how long 11 they take it.</p> <p>12 Q. Do you agree that an advantage of the 13 TVT retropubic device is reduced hospitalization?</p> <p>14 A. Disagree.</p> <p>15 Q. Why is that?</p> <p>16 A. Based upon Amaro, et al., that 17 hospital duration was the same for the TVT and the 18 autologous pubovaginal sling.</p> <p>19 Q. Do you know of other TVT versus 20 autologous pubovaginal sling randomized control 21 trials?</p> <p>22 A. As I sit here right now, I'm not 23 aware. I'd have to go back and look at the 24 literature.</p> <p>25 Q. In general, not isolated to a single</p>	<p>1 highly debatable.</p> <p>2 Q BY MR. SNELL: When you see "voiding 3 dysfunction" -- and this is written by the 4 organization that you belong to; right?</p> <p>5 A. Oh, yeah, and I know the people who 6 wrote it. One's on staff with me.</p> <p>7 Q. When you see the term "voiding 8 dysfunction" -- Mr. Cartmell objected as vague. 9 What did the AUA mean by "voiding 10 dysfunction" in this position statement.</p> <p>11 MR. CARTMELL: Object to the form.</p> <p>12 A. Yeah, when these guys and women get 13 together, this is a big argument, because, again, 14 I know the people on this board and I'm at the 15 meetings. I don't go -- I'm not a member of this 16 and the guidelines.</p> <p>17 But voiding dysfunction can be 18 anything. Stress incontinence, overactive 19 bladder, urgency frequency, nocturnal enuresis, 20 bladder pain with urination. Voiding dysfunction 21 is very vague. And hence, the reason why Rovner, 22 et al., wrote up a follow-up article in this in 23 the AUA newsletter.</p> <p>24 Q BY MR. SNELL: Actually, Rovner's 25 follow-up was before this was reissued. You know</p>

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<p style="text-align: right;">Page 126</p> <p>1 that; right?</p> <p>2 A. This was were the --</p> <p>3 Q. October 2013.</p> <p>4 A. 2013 is the one I'm referring to.</p> <p>5 Q. This paper was issued after Rovner's</p> <p>6 commentary?</p> <p>7 A. Well, no, this is a revision of the</p> <p>8 original; wasn't it? I'd have to look at when the</p> <p>9 first one came out, and it's a revision of it.</p> <p>10 Update.</p> <p>11 Q. On the very back page, October 2013,</p> <p>12 revised. Correct?</p> <p>13 A. Yeah.</p> <p>14 Q. They state that "mesh-related</p> <p>15 complications can occur following polypropylene</p> <p>16 sling placement, but the rate of these</p> <p>17 complications is acceptably low."</p> <p>18 Do you see that?</p> <p>19 A. Yes, I do.</p> <p>20 Q. "It is the AUA's opinion that any</p> <p>21 restriction on the use of synthetic polypropylene</p> <p>22 mesh suburethral slings would be a disservice to</p> <p>23 women who choose surgical correction of SUI."</p> <p>24 Do you see that?</p> <p>25 A. Yes, I do.</p>	<p style="text-align: right;">Page 128</p> <p>1 you have used it?</p> <p>2 A. It's going to depend upon the</p> <p>3 procedure we are discussing, but when specifically</p> <p>4 in TVT, from my perspective, based upon the</p> <p>5 literature and what's out there, as far as</p> <p>6 degradation, et cetera, anything short of lifelong</p> <p>7 is going to be insufficient.</p> <p>8 MR. SNELL: I don't think -- move to</p> <p>9 strike as nonresponsive.</p> <p>10 Q BY MR. SNELL: I'm trying to get a</p> <p>11 definition from you. So when you use the term</p> <p>12 "short-term," what do you mean by that?</p> <p>13 A. Short-term specifically relative to</p> <p>14 polypropylene meshes --</p> <p>15 Q. Okay.</p> <p>16 A. -- because it is a permanent</p> <p>17 implantable device, shown to have degradation in</p> <p>18 Klinge, et al., up to 15 years, Ethicon's</p> <p>19 statement showing that degradation continues,</p> <p>20 contraction, et cetera. Anything less than</p> <p>21 lifelong, to me, is short-term and insufficient.</p> <p>22 Q. And you like to apply a different bar</p> <p>23 to the Burch colposuspension; correct?</p> <p>24 A. Burch and also the autologous</p> <p>25 because -- specifically because those are no</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. "Multiple case series and randomized</p> <p>2 control trials attest to the efficacy of synthetic</p> <p>3 polypropylene mesh slings at 5 to 10 years."</p> <p>4 Do you see that?</p> <p>5 A. Yes, I do.</p> <p>6 Q. "The efficacy is equivalent or</p> <p>7 superior to other surgical techniques." Correct?</p> <p>8 A. That's what it states, yes.</p> <p>9 Q. And you've seen literature and data</p> <p>10 that supports that statement?</p> <p>11 A. As it pertains to efficacy, I agree.</p> <p>12 I mean, equivalent, I think is fine. And superior</p> <p>13 is debatable, and you have to look at those</p> <p>14 specific studies, but I'm not going to argue that.</p> <p>15 Q. "There is no significant increase in</p> <p>16 adverse events observed over this period of</p> <p>17 follow-up"; correct?</p> <p>18 A. Yeah. And that's the actual key right</p> <p>19 there, "over this period of follow-up," which is</p> <p>20 short-term.</p> <p>21 Q. How do you define -- did I ask you how</p> <p>22 you define "short-term"? I know you've mentioned</p> <p>23 that term.</p> <p>24 A. Yeah.</p> <p>25 Q. Can you define "short-term" for me as</p>	<p style="text-align: right;">Page 129</p> <p>1 permanent implantable device. With that said, for</p> <p>2 example, when the ProteGen sling was used in the</p> <p>3 past, the Gortex sling was used in the past, then</p> <p>4 I would say for those, you need to have lifelong</p> <p>5 follow-up.</p> <p>6 Okay. But, again, when we're talking</p> <p>7 about autologous tissue, the patient's own, or</p> <p>8 Burch, where there's no tissue used, the</p> <p>9 products -- there's no product in there to have</p> <p>10 lifelong problems with.</p> <p>11 Q. So how do you define short-term as to</p> <p>12 the autologous and the Burch?</p> <p>13 A. Well, a minimum study criteria</p> <p>14 established about four, five years ago, said any</p> <p>15 study less than 12 months for sling procedures was</p> <p>16 insufficient.</p> <p>17 So, again, it depends on what you're</p> <p>18 looking at in a study. But if we're looking at</p> <p>19 efficacy, efficacy is a different story. Efficacy</p> <p>20 can be lifelong. But if we're looking at</p> <p>21 perioperative complications, then really two years</p> <p>22 out. Patients heal. But there is no written in</p> <p>23 stone what short-term, long-term is.</p> <p>24 Q. I was just following up, though,</p> <p>25 because you used those terms, and I want to know</p>

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<p>1 what it means to you.</p> <p>2 So what is short-term --</p> <p>3 A. Short-term --</p> <p>4 Q. -- in the context of an autologous</p> <p>5 pubovaginal sling?</p> <p>6 MR. CARTMELL: Are you talking about</p> <p>7 in the context of a study?</p> <p>8 MR. SNELL: Not a particular study.</p> <p>9 He says short-term.</p> <p>10 Q. BY MR. SNELL: I want to know what you</p> <p>11 mean by that.</p> <p>12 A. I understand.</p> <p>13 Q. You've told me about the TVT and</p> <p>14 stuff, and I hear you. But now I want to know</p> <p>15 what standard do you apply to the Burch when you</p> <p>16 say short-term?</p> <p>17 A. Less than 12 months.</p> <p>18 Q. Okay.</p> <p>19 A. Less than 12 months. Arguably, 24</p> <p>20 months.</p> <p>21 Q. And what do you mean -- strike that.</p> <p>22 What standard do you use for the</p> <p>23 definition of short-term with regard to the</p> <p>24 autologous pubovaginal sling?</p> <p>25 A. Same thing. 12 months definitively.</p>	<p>1 been discussed. Ethicon knows that. So that</p> <p>2 actually is a very good point. Perhaps Prolene is</p> <p>3 not safe product, as we've been told.</p> <p>4 MR. SNELL: Move to strike as</p> <p>5 non-responsive.</p> <p>6 Q. BY MR. SNELL: My question was: It's</p> <p>7 known that permanent sutures can degrade. In</p> <p>8 fact, it's known that permanent sutures can have</p> <p>9 suture erosion if employed with the Burch</p> <p>10 colposuspension or the autologous pubovaginal</p> <p>11 sling procedure; right?</p> <p>12 A. Incorrect.</p> <p>13 Q. You haven't seen publications by</p> <p>14 people like Ed McGuire and others that report</p> <p>15 suture erosions following an autologous</p> <p>16 pubovaginal sling at an average duration follow-up</p> <p>17 of greater than 24 months?</p> <p>18 A. If you're doing a pubovaginal sling in</p> <p>19 the classic way where it's described, where the</p> <p>20 Prolene sutures are high up in the abdomen, away</p> <p>21 from the bladder, there should be zero erosions.</p> <p>22 If somebody's doing a variant of it, that's a</p> <p>23 different story. I can't speak to that. Burch is</p> <p>24 the same thing. You have a Prolene suture, which</p> <p>25 we know degrades based upon studies, okay, which</p>
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<p>1 Arguably 24 months.</p> <p>2 Q. Okay. Is that for safety, too?</p> <p>3 A. Yes. But, again, we don't have any</p> <p>4 permanent implantable device with those other</p> <p>5 procedures. So perioperative morbidity is a more</p> <p>6 important issue.</p> <p>7 Q. Well, you know there can be permanent</p> <p>8 sutures placed at the time of the autologous</p> <p>9 pubovaginal sling or a Burch; correct?</p> <p>10 A. Yes. And those are --</p> <p>11 Q. And you know there can be suture or --</p> <p>12 MR. CARTMELL: Let him finish. Hold</p> <p>13 on? Yes, and those are?</p> <p>14 A. Yes, and those are usually Prolene</p> <p>15 sutures, which we've been told by Ethicon are</p> <p>16 safe. However, in my practice, I've had two</p> <p>17 patients develop suture granulomas; so I don't use</p> <p>18 them. I use Vicryl sutures.</p> <p>19 Q. BY MR. SNELL: And you know that</p> <p>20 suture erosion can occur with those -- any type of</p> <p>21 permanent suture; correct?</p> <p>22 A. Then that raises the very real</p> <p>23 possibility of those sutures causing degradation,</p> <p>24 inflammatory reaction, foreign body response,</p> <p>25 which we know happens in the dog model. That's</p>	<p>1 are outlined in my expert report. Ethicon knows</p> <p>2 it. Prolene, as a much suture, degrades. If you</p> <p>3 knot it up and put it by the bladder, you can have</p> <p>4 degradation, foreign body reaction, and then</p> <p>5 subsequently erosion. So, yes, the question is</p> <p>6 why.</p> <p>7 MR. SNELL: Move to strike as</p> <p>8 nonresponsive.</p> <p>9 Q. BY MR. SNELL: My question was: Do</p> <p>10 you know there are studies that report suture</p> <p>11 erosions by people who do the autologous</p> <p>12 pubovaginal sling, like Ed McGuire, that report</p> <p>13 suture erosions at a follow-up of greater than</p> <p>14 24 months?</p> <p>15 A. I would have to see that exact study</p> <p>16 and we'd have to review it, see how they did the</p> <p>17 study. But, again, it raises the issue of why</p> <p>18 that's occurring.</p> <p>19 Q. My question is: Do you know whether</p> <p>20 or not the data exists?</p> <p>21 A. I answered that and said I'd have to</p> <p>22 see the studies you're talking about and how they</p> <p>23 did the procedure.</p> <p>24 MR. CARTMELL: Lunch is ready when you</p> <p>25 are.</p>

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<p>1 MR. SNELL: Is it. Yeah, let's go 2 ahead and do lunch. 3 (Recessed from 12:30 p.m. to 4 1:01 p.m.) 5 (Exhibit 9 marked.) 6 Q BY MR. SNELL: Doctor, I've handed you 7 the Position Statement on mid-urethral 8 sling-Urethral Slings for Stress Urinary 9 Incontinence By IUGA. 10 You're familiar with this document? 11 A. Yes, I am. 12 Q. This is one of those professional 13 societies to which you belong today? 14 A. That is correct. 15 Q. And similar to the AUA statement that 16 we looked at, it talks about efficacy of the 17 mid-urethral slings; correct? 18 A. Correct. 19 Q. And it talks about safety of 20 mid-urethral slings; correct? 21 A. Yeah. It discusses it, yes. 22 Q. All right. In the third paragraph, 23 when they're talking about mid-urethral slings, 24 they state that "They have been shown to be as 25 effective as more invasive traditional surgery</p>	<p>1 mid-urethral slings from over 2,000 publications 2 making this treatment the most extensively 3 reviewed and evaluated procedure for female stress 4 urinary incontinence now in use." 5 Do you agree with that? 6 A. I have not looked at that. 7 Q. "These scientific publications studied 8 all types of patients, including those with 9 co-morbidities, such as prolapse, obesity, and 10 other types of bladder dysfunction." 11 Have you analyzed that? 12 A. Independently analyzed it, I've read 13 the studies concerning that. 14 Q. You haven't read all 2,000 15 publications they're referring to; correct? 16 A. No. That is correct. Yes. 17 Q. It says, "It is, however, acknowledged 18 that any operation can cause complications." 19 And that's a fair statement; correct? 20 A. There can be different sets of 21 complications, but any procedure can have 22 complications. 23 Q. "For mid-urethral slings these include 24 bleeding, damage to the bladder and bowel, voiding 25 difficulty, tape exposure and pelvic pain; all of</p>
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<p>1 with major advantages of shorter operating and 2 admission times and a quicker return to normal 3 activities together with lower rates of 4 complications." 5 Do you see that? 6 A. Yes, I do. 7 Q. Do you disagree with the IUGA position 8 statement? 9 A. I disagree. 10 Q. "This has resulted in the mid-urethral 11 sling becoming the operation of choice in Europe, 12 Asia, South America, South Africa, Australasia," 13 A-u-s-t-r-a-l-a-s-i-a, "and North America for the 14 treatment of SUI with several million procedures 15 performed worldwide." 16 Do you see that? 17 A. Yes, I do. 18 Q. Do you agree or disagree with that 19 statement that it is the operation of choice as 20 amongst the alternative surgeries? 21 A. It is the most common procedure -- 22 Q. Okay. 23 A. -- I mean, performed. 24 Q. A little further down it says, "There 25 is robust evidence to support the use of</p>	<p>1 these may require repeat surgery, but this is 2 uncommon." 3 Do you see that? 4 A. Yes, I do. 5 Q. A little further down, they talk about 6 "long-term effectiveness of up to 80 percent has 7 been demonstrated in studies including one which 8 has followed up a small group of patients for 9 17 years"; correct? 10 A. That's what it states, yes. 11 Q. And in this IUGA statement has a list 12 of references -- do you have that? All right. 13 So for the 17-year study, you 14 understand that to be the Nilsson paper on the TVT 15 retropubic study? 16 A. That's the only 17-year one. I'll 17 make an argument that it's not TVT. 18 Q. What argument would you make that it's 19 not TVT? 20 A. Based upon the deposition by Arnaud 21 who said it's not a TVT product. And he doesn't 22 know if it's the polypropylene mesh even used by 23 Ethicon -- or manufactured by Ethicon. 24 Q. Do you have any -- have you done any 25 independent confirmation of whether or not that</p>

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<p>1 product was TVT other than what you just</p> <p>2 referenced with regard to Dr. Axel Arnaud's</p> <p>3 deposition testimony?</p> <p>4 A. The only way I'd have access to that</p> <p>5 is via the deposition. It's impossible to know</p> <p>6 that in another independent source, but since Axel</p> <p>7 Arnaud is very high up in Ethicon and he states</p> <p>8 it's not TVT, I'm going to believe him.</p> <p>9 Q. Do you know whether that mesh was a</p> <p>10 Prolene -- polypropylene mesh?</p> <p>11 A. It was a polypropylene mesh, as what</p> <p>12 he said. Maybe made by Ethicon. Maybe made by</p> <p>13 Bard. He doesn't know.</p> <p>14 Q. As a result IUGA supports the use of</p> <p>15 monofilament polypropylene mid-urethral slings for</p> <p>16 the surgical treatment of female stress urinary</p> <p>17 incontinence."</p> <p>18 Do you see that?</p> <p>19 A. Yes, I do.</p> <p>20 Q. Do you agree or disagree with IUGA's</p> <p>21 support?</p> <p>22 A. Disagree.</p> <p>23 Q. You've read the AUGS and SUFU</p> <p>24 statement on mid-urethral slings?</p> <p>25 A. Yes, I have.</p>	<p>1 A. Correct. In June of 2013.</p> <p>2 Q. Did you have to study for that exam?</p> <p>3 A. Yes, I did.</p> <p>4 Q. Did part of that exam testing concern</p> <p>5 polypropylene mid-urethral slings?</p> <p>6 A. Yes.</p> <p>7 Q. Was part of that exam concerning the</p> <p>8 Burch colposuspension and the autologous</p> <p>9 pubovaginal sling?</p> <p>10 A. It's been two years, and I can't</p> <p>11 recall exactly. I know they had Burch questions</p> <p>12 and I know they had sling questions, yes.</p> <p>13 Q. This says, "The polypropylene mesh</p> <p>14 mid-urethral sling is the recognized worldwide</p> <p>15 standard of care for the surgical treatment of</p> <p>16 stress urinary incontinence."</p> <p>17 Do you see that? On the first page.</p> <p>18 A. Unfortunately, no, I don't see it.</p> <p>19 Q. Here.</p> <p>20 A. I listen to -- oh, there on the bold.</p> <p>21 Yes. I see it.</p> <p>22 Q. And you would agree it's within the</p> <p>23 standard of care for a female urologist or a</p> <p>24 pelvic floor surgeon to do a polypropylene mesh</p> <p>25 mid-urethral sling like the TVT retropubic today?</p>
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<p>1 (Exhibit 10 marked.)</p> <p>2 Q. BY MR. SNELL: You don't belong to</p> <p>3 AUGS, but you do belong to SUFU; right?</p> <p>4 A. That -- yeah. They're sister</p> <p>5 societies. So I can attend AUGS meetings as a</p> <p>6 member, but I am not formally in their membership</p> <p>7 role.</p> <p>8 Q. SUFU has over 500 members?</p> <p>9 A. I don't know the number. It's a lot.</p> <p>10 Q. AUGS -- do you know whether they</p> <p>11 represent more than 1,700 members?</p> <p>12 A. They have a lot. They have more than</p> <p>13 SUFU.</p> <p>14 Q. Do you have to be a urogynecologist or</p> <p>15 to have passed a subspecialty female pelvic</p> <p>16 medicine or reconstructive surgery boards to be a</p> <p>17 member of AUGS as opposed to SUFU?</p> <p>18 A. No. You can be a member of AUGS</p> <p>19 without having any credentials. To take the board</p> <p>20 exam, the female pelvic medicine reconstructive</p> <p>21 surgery, you just have to supply certain logs,</p> <p>22 have a certain amount of volume of cases and take</p> <p>23 the exam.</p> <p>24 Q. You took that exam and passed it;</p> <p>25 right?</p>	<p>1 A. It is not malpractice to do that</p> <p>2 procedure.</p> <p>3 Q. It, therefore, is within the standard</p> <p>4 of care; correct?</p> <p>5 MR. CARTMELL: Object to the form.</p> <p>6 A. Well, as I said, it's not going to be</p> <p>7 malpractice. It is an accepted treatment out</p> <p>8 there.</p> <p>9 Q. BY MR. SNELL: You've reviewed --</p> <p>10 well, let me ask you: Have you reviewed the AUA</p> <p>11 stress urinary incontinence guidelines?</p> <p>12 A. Yeah. It depends which year you're</p> <p>13 talking about. There's 2009 and others.</p> <p>14 Q. The 2009 and then the update in 2012?</p> <p>15 A. Yes. Yes.</p> <p>16 Q. All right. I think you pronounced the</p> <p>17 lead author's name --</p> <p>18 A. Oh, Dmochowski. Call him Roger.</p> <p>19 Q. For example, in those AUA stress</p> <p>20 urinary incontinence guidelines, they recognize</p> <p>21 mid-urethral, retropubic, trans -- they -- strike</p> <p>22 that.</p> <p>23 In the AUA stress urinary incontinence</p> <p>24 guidelines they recognize the retropubic</p> <p>25 polypropylene mid-urethral sling like the TVT</p>

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<p>1 retropubic as being a suitable surgical option for</p> <p>2 surgeons to turn to; correct?</p> <p>3 A. Yeah. Using the terminology you did,</p> <p>4 it is one of the treatment options available.</p> <p>5 Q. And they looked at the literature, did</p> <p>6 a systematic review, and they analyzed the data on</p> <p>7 mid-urethral slings, Burch, and the autologous</p> <p>8 pubovaginal slings, and came to that conclusion?</p> <p>9 A. Yes. They analyzed more than just</p> <p>10 those, but, yes, those are some of the ones they</p> <p>11 analyzed.</p> <p>12 Q. Those were the main groups that they</p> <p>13 reported on; correct?</p> <p>14 A. I'd have to look at your question --</p> <p>15 it was, you know, retropubic, transobturator,</p> <p>16 pubovaginal, and Burch.</p> <p>17 Q. Right. In the AUGS/SUFU statement</p> <p>18 they say, "The procedure is safe, effective, and</p> <p>19 has improved the quality of life for millions of</p> <p>20 women."</p> <p>21 Do you see that? I'm sorry. Right</p> <p>22 where we were at.</p> <p>23 A. Oh, I'm sorry. Yes, I see that.</p> <p>24 Q. Do you agree or disagree with</p> <p>25 AUGS/SUFU?</p>	<p>1 MR. CARTMELL: He answered it.</p> <p>2 Objection. Asked and answered.</p> <p>3 We're reading it. He says that are</p> <p>4 "currently available on the market, I agree with</p> <p>5 you, they are all unsafe."</p> <p>6 MR. SNELL: He's not agreeing with me,</p> <p>7 because I didn't posit the question as "please</p> <p>8 agree with me." I'm just asking his opinion.</p> <p>9 Q. BY MR. SNELL: Understand. So let me</p> <p>10 just -- let's just strike that and make sure we</p> <p>11 get a clean Q and A.</p> <p>12 Do you believe, Dr. Elliott, that all</p> <p>13 of the polypropylene mesh mid-urethral slings</p> <p>14 available for the treatment of female stress</p> <p>15 urinary incontinence are unsafe?</p> <p>16 A. I believe that all the currently</p> <p>17 available mesh slings available on the market as</p> <p>18 of right now and their technique are unsafe.</p> <p>19 Q. You do not disagree, I take it, that</p> <p>20 some women can have, following the TVT retropubic</p> <p>21 placement, cure of their incontinence and</p> <p>22 improvement in quality of life?</p> <p>23 MR. CARTMELL: Object to the form.</p> <p>24 A. It is a hypothetical individual, but</p> <p>25 there are going to be studies that show, as of</p>
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<p>1 A. Disagree.</p> <p>2 Q. You disagree that the procedure is</p> <p>3 effective?</p> <p>4 A. No.</p> <p>5 Q. Do you disagree that the procedure has</p> <p>6 improved the quality of lives for millions of</p> <p>7 women?</p> <p>8 A. I have no way of proving that.</p> <p>9 Q. You disagree the procedure is safe?</p> <p>10 A. Yes.</p> <p>11 Q. And do you believe that all</p> <p>12 polypropylene mesh mid-urethral slings are unsafe?</p> <p>13 A. That are currently available on the</p> <p>14 market now, I agree with you they are all unsafe.</p> <p>15 Q. Let me rephrase that. I don't think I</p> <p>16 asked you to agree with me.</p> <p>17 MR. CARTMELL: You did.</p> <p>18 MR. SNELL: No, I didn't. I think --</p> <p>19 MR. CARTMELL: Do you disagree?</p> <p>20 MR. SNELL: Disagree the procedure is</p> <p>21 safe, yes.</p> <p>22 Q. BY MR. SNELL: All right. My question</p> <p>23 was: And do you believe that all polypropylene</p> <p>24 mesh mid-urethral slings are unsafe?</p> <p>25 A. Okay. All the --</p>	<p>1 right now, they have had -- they've reached that.</p> <p>2 The question is what will happen with long-term</p> <p>3 follow-up.</p> <p>4 Q. BY MR. SNELL: Do you only treat</p> <p>5 female stress incontinence or do you also treat</p> <p>6 male stress incontinence?</p> <p>7 A. I treat both female and male voiding</p> <p>8 dysfunction.</p> <p>9 Q. Do males have stress urinary</p> <p>10 incontinence?</p> <p>11 A. Following prostate surgery. Almost</p> <p>12 exclusively that's what I see them for.</p> <p>13 Q. Do you use any medical devices for the</p> <p>14 treatment of male stress urinary incontinence?</p> <p>15 A. Yes. The AMS800 -- American Medical</p> <p>16 Systems 800 artificial urinary sphincter.</p> <p>17 Q. And are there any lifelong registries</p> <p>18 monitoring those patients?</p> <p>19 A. Yes. The AMS -- American Medical</p> <p>20 Systems keeps a registry of all implants. Every</p> <p>21 time I do a surgery on them, they are notified,</p> <p>22 and I have to fill out a summary of what I did,</p> <p>23 revision, complications, et cetera.</p> <p>24 Q. Do those track the patients lifelong?</p> <p>25 A. Yes.</p>

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<p>1 Q. Where is that data published, if at 2 all?</p> <p>3 A. It is not published. It's at AMS. 4 American Medical Systems, which is based in 5 Minnetonka, Minnesota. And that goes back to 6 1972.</p> <p>7 (Exhibit 11 marked.)</p> <p>8 Q BY MR. SNELL: I've handed you 9 Exhibit 11. This is the AUGS -- one of the AUGS 10 position statements; correct?</p> <p>11 A. Correct. This one is on pelvic floor 12 disorders, though.</p> <p>13 Q. If you look at paragraph 5 where they 14 talk about stress urinary incontinence and mesh 15 slings.</p> <p>16 A. On page 3, I think?</p> <p>17 Q. Yes.</p> <p>18 A. I'm there.</p> <p>19 Q. It says, "Full length mid-urethral 20 slings, both retropubic and transobturator" -- and 21 just so we're clear, the TVT retropubic is a full 22 length retropubic mid-urethral sling; correct?</p> <p>23 A. I'm sorry to interrupt you. I just 24 don't know where you are -- I see the paragraph. 25 I just don't know which --</p>	<p>1 sentence?</p> <p>2 A. That is outlined in detail in my 3 expert report, going to all those various issues. 4 The extensively studied, I agree with. 5 Safe, I disagree with, as mentioned in 6 my expert report, my clinical experience, my 7 discussion in national and international meetings. 8 Effective relative to other treatment 9 options, I agree with. We've established that 10 already.</p> <p>11 Remains a leading treatment 12 opposition, I agree. It is common, the use. I 13 don't have a problem with that.</p> <p>14 Current gold standard of care for 15 stress urinary incontinence. Gold standard means 16 absolutely nothing to me. I don't even know what 17 that means. The term gets thrown around a lot.</p> <p>18 Is it something that is compared to?</p> <p>19 It is the best. So it is -- I agree with the 20 leading treatment option. There are other things 21 that are available that it could be compared to. 22 Burch sling or the TVT.</p> <p>23 Q. The term "gold standard," that's 24 something that you've seen commonly in the medical 25 literature; correct?</p>
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<p>1 Q. The bottom five, six lines.</p> <p>2 A. Starting --</p> <p>3 Q. Actually, the bottom three lines.</p> <p>4 That's okay.</p> <p>5 A. Starting with "Full-length," yes.</p> <p>6 Q. Okay. The TVT retropubic device is a 7 full length retropubic mid-urethral sling; right?</p> <p>8 A. Okay. I'm sorry. I was trying to 9 find where you -- I thought you were reading. I'm 10 sorry.</p> <p>11 The question was, is the 12 full-length -- well, I don't necessarily know what 13 they mean by a full length. Everything is a full 14 length, whether it's short or long, but this is 15 the longest length of mesh.</p> <p>16 Q. It says they "have been extensively 17 studied, are safe and effective relative to other 18 treatment options and remain the leading treatment 19 option and current gold standard of care for 20 stress incontinence surgery"; correct?</p> <p>21 A. That's what they state, yes.</p> <p>22 Q. Do you disagree or agree with AUGS?</p> <p>23 A. I disagree.</p> <p>24 Q. What exactly do you disagree with 25 there in that paragraph -- sorry. In that</p>	<p>1 A. It is thrown around extensively. It's 2 a bad term.</p> <p>3 Q. You've seen people refer to the 4 autologous pubovaginal sling as a gold standard; 5 correct?</p> <p>6 A. Correct.</p> <p>7 Q. You've seen people refer to the Burch 8 colposuspension as the gold standard; correct?</p> <p>9 A. Correct.</p> <p>10 Q. You've seen people refer to the TVT 11 retropubic device as a gold standard; correct?</p> <p>12 A. Correct.</p> <p>13 Q. To your knowledge or understanding, is 14 there a -- strike that.</p> <p>15 To your knowledge and understanding, 16 what does it mean to be a gold standard within the 17 art of pelvic surgery?</p> <p>18 A. It should be -- this is my 19 interpretation of it.</p> <p>20 Gold standard should be the procedure 21 that has the safest, the best, which everything 22 should be compared to. The gold standard, unlike 23 gold. Gold cannot -- the true iron -- or true 24 element cannot be replaced. Okay. Gold standards 25 have evolved.</p>

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<p>1 In the '90s, it was the Raz, R-a-z,</p> <p>2 urethropexy. That's gone now. So gold standard</p> <p>3 is a shifting thing. It's what everything should</p> <p>4 be compared to because it has proven itself to be</p> <p>5 the best in all factors involved.</p> <p>6 Q. Back when the Raz urethropexy was</p> <p>7 reported in the literature, there weren't any</p> <p>8 randomized control trials in that procedure,</p> <p>9 comparing it to the Burch and pubovaginal sling;</p> <p>10 correct?</p> <p>11 A. I'd have to look at the literature. I</p> <p>12 don't recall any.</p> <p>13 Q. Did people refer to, like, the Raz</p> <p>14 procedure as the gold standard, not based on</p> <p>15 comparative -- direct comparative data?</p> <p>16 A. The gold standard relative to urinary</p> <p>17 incontinence has really evolved since TVT came</p> <p>18 out. And that's when there was now a comparison.</p> <p>19 You had some people were for Burch, some people</p> <p>20 for sling, some people for the Raz. The Raz fell</p> <p>21 out. Wasn't effective. Then TVT was around.</p> <p>22 Then the argument came of this gold standard.</p> <p>23 But, again, it's not like you can type up a paper</p> <p>24 and put in equations and come up with, oh, this</p> <p>25 one's gold. It's relative.</p>	<p>1 correct?</p> <p>2 A. That is correct.</p> <p>3 Q. And have you reviewed this document</p> <p>4 before?</p> <p>5 A. Yes, I have.</p> <p>6 Q. Okay. Were you involved in the</p> <p>7 drafting of this document?</p> <p>8 A. No, I was not. And the interesting</p> <p>9 thing is, being a member of the female urology</p> <p>10 section, I don't recognize very many of these</p> <p>11 names.</p> <p>12 Q. This was published in 2012; right?</p> <p>13 A. Yes.</p> <p>14 Q. And what they did was, using their</p> <p>15 methodology, they used evidence-based medicine</p> <p>16 methodology and did individual literature search</p> <p>17 strategies?</p> <p>18 A. Correct. For the treatment of both</p> <p>19 men and women.</p> <p>20 Q. Fair enough.</p> <p>21 And for the treatment of stress</p> <p>22 urinary incontinence in women, they concluded that</p> <p>23 mid-urethral slings should be offered as the first</p> <p>24 line treatment; correct?</p> <p>25 A. I'd have to see where you're quoting.</p>
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<p>1 Q. There are other procedures for stress</p> <p>2 urinary incontinence that have also fallen out of</p> <p>3 favor, like the MMK that you earlier referenced;</p> <p>4 correct?</p> <p>5 A. Correct. There are many that have</p> <p>6 faded away.</p> <p>7 Q. The anterior repair is another;</p> <p>8 correct?</p> <p>9 A. Well, I don't know if you're talking</p> <p>10 about the Kennedy Kelly plication. That is still</p> <p>11 done somewhat, but it's not, what you would say,</p> <p>12 in the upper tier of effective treatments.</p> <p>13 Q. And that would be based on randomized</p> <p>14 control trial data or cohort studies?</p> <p>15 A. Cohort studies.</p> <p>16 MR. SNELL: Let's mark this as the</p> <p>17 next one.</p> <p>18 (Exhibit 12 marked.)</p> <p>19 Q BY MR. SNELL: Exhibit 12 is the EAU</p> <p>20 Guidelines on Surgical Treatment of stress --</p> <p>21 strike that.</p> <p>22 EAU Guidelines -- let me get a better</p> <p>23 question out.</p> <p>24 Exhibit 12 is the EAU Guidelines on</p> <p>25 Surgical Treatment of Urinary Incontinence;</p>	<p>1 I just don't see it in the document. The</p> <p>2 document's fairly long.</p> <p>3 Q. Okay. The third page, go to the</p> <p>4 surgical algorithm.</p> <p>5 A. Yes.</p> <p>6 Q. Where you see if a person has -- a</p> <p>7 woman; right? The top diagram is for treatment in</p> <p>8 women; right?</p> <p>9 A. Correct.</p> <p>10 Q. And for stress incontinent women,</p> <p>11 first line is "Offer mid-urethral sling"; correct?</p> <p>12 A. Yeah. Or "consider peri-urethral</p> <p>13 injections"; right.</p> <p>14 Q. Right. So mid-urethral sling would be</p> <p>15 a first-line surgical option for the treatment of</p> <p>16 stress urinary incontinence in women, according to</p> <p>17 the EAU Guidelines; correct?</p> <p>18 A. Yeah. Yes. This algorithm,</p> <p>19 established in 2012, that is what they offer as</p> <p>20 first-line treatment.</p> <p>21 Q. And they also identify the</p> <p>22 mid-urethral sling as a first-line surgical option</p> <p>23 if there's mixed incontinence, but the stress is</p> <p>24 predominant; correct?</p> <p>25 A. Yes.</p>

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<p>1 Q. And do you disagree with the EAU</p> <p>2 Guidelines in that regard?</p> <p>3 A. Yes, I do.</p> <p>4 (Exhibit 13 marked.)</p> <p>5 Q BY MR. SNELL: This is the Guidelines</p> <p>6 on Urinary Incontinence from the EAU 2015.</p> <p>7 Do you see that?</p> <p>8 A. Yes, I do.</p> <p>9 Q. So this is when you were in your role</p> <p>10 in that pertinent group; correct?</p> <p>11 A. That's correct.</p> <p>12 Q. First page says, "Mid-urethral slings</p> <p>13 are now the most frequently used surgical</p> <p>14 intervention in Europe for women with stress</p> <p>15 urinary incontinence."</p> <p>16 Do you see that?</p> <p>17 A. I don't see it. But I heard you read</p> <p>18 it. Okay. Yes. Yes, I see it. Yes.</p> <p>19 Q. And for the purpose of the guidelines,</p> <p>20 they did a new meta-analysis; correct?</p> <p>21 A. Correct.</p> <p>22 Q. Were you consulted on these</p> <p>23 guidelines?</p> <p>24 A. No, I was not.</p> <p>25 Q. But these are people who are in the</p>	<p>1 A. Yes, I do.</p> <p>2 Q. ICS is another organization you belong</p> <p>3 to; correct?</p> <p>4 A. That is correct.</p> <p>5 Q. And so they cover different</p> <p>6 conditions, like overactive bladder, and then they</p> <p>7 have stress urinary incontinence beginning on</p> <p>8 page 12.</p> <p>9 A. Yes.</p> <p>10 Q. Have you seen these before?</p> <p>11 A. Um-hum. Yes, I have.</p> <p>12 Q. Do you use these statements with any</p> <p>13 of your patients?</p> <p>14 A. No.</p> <p>15 Q. I know ACOG and the Urology</p> <p>16 Foundation, the branch of the AUA, have patient</p> <p>17 guides, publications, things like that.</p> <p>18 Do you use any of those materials with</p> <p>19 your patients?</p> <p>20 A. We have them available for education</p> <p>21 purposes. We'll go through it. But to be honest,</p> <p>22 usually that's so overwhelming for the average</p> <p>23 individual that we don't rely on them heavily.</p> <p>24 Q. Does Mayo Clinic have its own patient</p> <p>25 education handouts that you use --</p>
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<p>1 group that you belong to?</p> <p>2 A. They're in -- members of the EAU. But</p> <p>3 these are not people in the subsection of female</p> <p>4 urology and functional urology. And I'm on the</p> <p>5 board of those. And I know some of their names,</p> <p>6 but they're not sitting on the board.</p> <p>7 Q. Were you even aware that these urinary</p> <p>8 incontinence guidelines were published in 2015 by</p> <p>9 EAU?</p> <p>10 A. No. I was aware they were published.</p> <p>11 I was not part of their publishing.</p> <p>12 Q. Does the EAU still recognize the</p> <p>13 mid-urethral polypropylene slings as a surgical</p> <p>14 option to treat stress urinary incontinence?</p> <p>15 A. Yes. As stated in their document,</p> <p>16 they do not ban its use.</p> <p>17 Q. Do they still, as of today, recognize</p> <p>18 the mid-urethral polypropylene sling as being the</p> <p>19 appropriate first-line surgical option?</p> <p>20 A. That's what they state in the previous</p> <p>21 document. I don't know about this one.</p> <p>22 (Exhibit 14 marked.)</p> <p>23 Q. BY MR. SNELL: So these are the fact</p> <p>24 sheets by ICS published July 2013.</p> <p>25 Do you see that?</p>	<p>1 A. Yeah. We have a --</p> <p>2 Q. -- for stress urinary incontinence?</p> <p>3 That's what I'm focused on.</p> <p>4 A. We have an overarching, for</p> <p>5 incontinence. Within it is a subsection of stress</p> <p>6 incontinence. But it's not specific just to</p> <p>7 stress.</p> <p>8 Q. Okay. On page 13 where they're</p> <p>9 talking about -- it says, "Definitive therapy for</p> <p>10 SUI is surgical."</p> <p>11 A. Correct.</p> <p>12 Q. You would agree with that; correct?</p> <p>13 MR. CARTMELL: I'm sorry. What was</p> <p>14 the question again?</p> <p>15 A. Definitive area for SUI is the</p> <p>16 surgical?</p> <p>17 Q. BY MR. SNELL: No. Let me repeat it.</p> <p>18 It's not "area."</p> <p>19 This states on page 13, "Definitive</p> <p>20 therapy for SUI is surgical."</p> <p>21 Do you see that?</p> <p>22 A. No. I see it.</p> <p>23 Q. Do you agree with that?</p> <p>24 A. I'd say no. It is -- surgery is an</p> <p>25 option for some individuals. But some individuals</p>

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<p>1 with appropriate counseling do not need to have</p> <p>2 surgery. So depends how you're defining</p> <p>3 definitive, I suppose. There are other things</p> <p>4 that work.</p> <p>5 Q. Right. So pelvic floor exercises;</p> <p>6 correct?</p> <p>7 A. Correct. That's one of them.</p> <p>8 Q. And bulking agents; correct?</p> <p>9 A. Correct.</p> <p>10 Q. And you're aware of data showing</p> <p>11 surgical -- when you compare stress urinary</p> <p>12 incontinence surgery, the efficacy of that</p> <p>13 compared to those alternatives, non-surgical</p> <p>14 alternatives, surgery has better results?</p> <p>15 A. Correct. I agree with that. I just</p> <p>16 have a problem with definitive therapy.</p> <p>17 Q. Right.</p> <p>18 A. It's a little too dogmatic for me.</p> <p>19 Q. Okay. "Worldwide, mid-urethral slings</p> <p>20 comprised of synthetic mesh have become the</p> <p>21 treatment of choice for SUI."</p> <p>22 And we've already discussed that;</p> <p>23 right?</p> <p>24 A. Ad nauseam, yes.</p> <p>25 Q. "Long-term data are robust and</p>	<p>1 A. Yes, that is a fair statement.</p> <p>2 Q. And I mean, you're a better surgeon,</p> <p>3 don't you think, today than when you were coming</p> <p>4 out of your fellowship; correct?</p> <p>5 A. Correct.</p> <p>6 Q. And part of that is because you've</p> <p>7 amassed more surgical volume experience; correct?</p> <p>8 A. That is one aspect of it. And I have</p> <p>9 read hundreds of journal articles, attend all the</p> <p>10 national and international meetings, and discuss</p> <p>11 with high level colleagues. But, yes, there</p> <p>12 should be progress. But individuals who don't</p> <p>13 have the advantages I do, aren't necessarily going</p> <p>14 to progress. They could actually worsen.</p> <p>15 (Exhibit 15 marked.)</p> <p>16 Q BY MR. SNELL: This is the NICE,</p> <p>17 N-I-C-E, Clinical Guideline 171 issued</p> <p>18 September 2013 on urinary incontinence in women.</p> <p>19 Are you familiar with this?</p> <p>20 A. Yes, I am.</p> <p>21 Q. Turn to page 24.</p> <p>22 A. Okay.</p> <p>23 Q. And just as background, you're aware</p> <p>24 then that in the generation of this NICE guideline</p> <p>25 they searched the medical literature?</p>
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<p>1 demonstrate durable efficacy with a very low</p> <p>2 complication rate, particularly in experienced</p> <p>3 hands."</p> <p>4 You would agree with that?</p> <p>5 MR. CARTMELL: Object to the form.</p> <p>6 A. I agree with parts and disagree with</p> <p>7 other parts. So in totality, I would have to say</p> <p>8 I disagree.</p> <p>9 Q BY MR. SNELL: What do you agree with</p> <p>10 in that sentence?</p> <p>11 A. Long-term -- oh, what do I agree with?</p> <p>12 Sorry.</p> <p>13 Q. Yes.</p> <p>14 A. I think, as we established, "durable</p> <p>15 efficacy," I'm okay with that.</p> <p>16 And then, "particularly in experienced</p> <p>17 hands," as I've stated before, more experienced</p> <p>18 surgeons, the data is very clear. Arnaud even</p> <p>19 admitted they're going to have better results.</p> <p>20 "Very low complication rates," I</p> <p>21 disagree with. Strongly.</p> <p>22 Q. For any type of stress incontinence</p> <p>23 surgery, we can agree that more experienced</p> <p>24 surgeons are going to typically give better</p> <p>25 results; right?</p>	<p>1 A. Yes. They have done similar to what</p> <p>2 the AUA guidelines are. All these societies do</p> <p>3 essentially the same thing.</p> <p>4 Q. And they say for when offering --</p> <p>5 strike that.</p> <p>6 They state, paragraph 1.10.3, "When</p> <p>7 offering a synthetic mid-urethral tape procedure</p> <p>8 surgeons should: Use procedures and devices for</p> <p>9 which there is current high quality evidence of</p> <p>10 efficacy and safety."</p> <p>11 Do you see that?</p> <p>12 A. Yes, and I agree with that statement.</p> <p>13 Q. They also say use only -- "only use a</p> <p>14 device that they have been trained to use."</p> <p>15 Do you agree with that?</p> <p>16 A. Yes, I do.</p> <p>17 Q. Do you use any devices that you</p> <p>18 weren't trained on?</p> <p>19 A. No.</p> <p>20 Q. "Use a device manufactured from type 1</p> <p>21 macroporous polypropylene tape."</p> <p>22 Do you agree with that?</p> <p>23 A. If he's referring to the Amid type 1,</p> <p>24 I disagree with that.</p> <p>25 Q. Well, there's no other type 1 system</p>

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<p>1 that reports and identifies macroporous versus</p> <p>2 microporous than Amid; correct?</p> <p>3 A. There is no industry standard</p> <p>4 regarding that. However, I'm stating that Amid is</p> <p>5 archaic. So macroporous is a relative term. We</p> <p>6 have to define what macroporous is.</p> <p>7 Q. So there is no -- so macroporous means</p> <p>8 macro, large; porous, pores; correct?</p> <p>9 A. That is the literal translation of the</p> <p>10 word, yes.</p> <p>11 Q. And in the Amid classification,</p> <p>12 macroporous is defined as greater or equal to</p> <p>13 75 microns; is that correct?</p> <p>14 A. Yeah. Yeah. Greater than or equal</p> <p>15 to, yeah, that's what Amid does.</p> <p>16 Q. And that's because the cells involved</p> <p>17 in tissue ingeneration, combating bacteria are all</p> <p>18 cells that are smaller than 75 microns; correct?</p> <p>19 A. Well, I mean, it goes beyond that,</p> <p>20 that the 75 microns and be able to have the</p> <p>21 inflammatory responders, be able to perforate</p> <p>22 through that.</p> <p>23 But, again, the data shows, Ethicon</p> <p>24 agrees as stating, that it's 1,000 microns now and</p> <p>25 a minimum under strain. So what I'm saying is the</p>	<p>1 MR. CARTMELL: Let him answer.</p> <p>2 A. And I'm saying, if all that were true,</p> <p>3 we would not be sitting here with all the</p> <p>4 degradation problems and inflammatory responses.</p> <p>5 And then I know what I read with Ethicon</p> <p>6 depositions, that they all agree that is too small</p> <p>7 and that is not the standard they go by. So all</p> <p>8 I'm saying is I do not agree with this as it's</p> <p>9 stated.</p> <p>10 Q BY MR. SNELL: But my question to you</p> <p>11 is: Based on your knowledge and scientific</p> <p>12 understanding, can macrophages extend pseudopodia</p> <p>13 to try to get to bacteria in spaces less than</p> <p>14 5 microns?</p> <p>15 A. They can try, but are they successful?</p> <p>16 Q. Are they --</p> <p>17 A. And this is -- this is 75 microns when</p> <p>18 it comes out of the box. But that's not under</p> <p>19 stress. So it decreases. So, again, where</p> <p>20 they're really insufficient and where I have privy</p> <p>21 to information is not what it comes out of the</p> <p>22 box, when it's been implanted in the woman and</p> <p>23 after contraction of scarring.</p> <p>24 Q. The pore size in the mesh for TVT is</p> <p>25 much larger than 75 microns out of the box. We</p>
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<p>1 Amid is archaic, and not the standard used</p> <p>2 anymore.</p> <p>3 Q. Do any of the professional societies</p> <p>4 that you belong to state and define macroporous as</p> <p>5 anything other than that which the Amid</p> <p>6 classification states it as, greater than or equal</p> <p>7 to 75 microns?</p> <p>8 A. I have yet to see that in any of the</p> <p>9 society statements that they state that because</p> <p>10 they don't know the information I've been privy</p> <p>11 to.</p> <p>12 Q. We can agree that those inflammatory</p> <p>13 cells are all smaller than 75 microns; correct?</p> <p>14 MR. CARTMELL: Object to the form.</p> <p>15 A. Not necessarily, because some of the</p> <p>16 macrophages, especially under activated states,</p> <p>17 can be up to 80 micrometers or greater.</p> <p>18 Q BY MR. SNELL: Well, you know</p> <p>19 macrophages can enhance pseudopodia, which can get</p> <p>20 into spaces that are less than 5 microns; don't</p> <p>21 you.</p> <p>22 A. Then if all that were true --</p> <p>23 Q. Answer my question. Do you know that</p> <p>24 or not?</p> <p>25 A. I was answering your question.</p>	<p>1 can agree to that.</p> <p>2 A. Out of the box, I have seen numbers</p> <p>3 all over the board because they don't have a --</p> <p>4 there's not a circle with a diameter. There's</p> <p>5 wires or fibers going everywhere. So there's not</p> <p>6 a uniform size. So you may have one greater than</p> <p>7 75. Right next to it, you have one at 10 microns.</p> <p>8 And that's what P.A. Newell said under oath.</p> <p>9 Q. Have you ever put the TVT mesh out of</p> <p>10 the box next to a millimeter ruler and looked --</p> <p>11 A. Yes.</p> <p>12 Q. -- and seen whether the pores are</p> <p>13 larger than a millimeter?</p> <p>14 A. Absolutely, I have.</p> <p>15 Q. And those pores are larger than a</p> <p>16 millimeter out of the box; correct?</p> <p>17 A. Absolutely not. A millimeter?</p> <p>18 Q. Yes. 100 microns for a TVT.</p> <p>19 A. Out of the box. You might be able to</p> <p>20 find some, but right next to it it's not. But,</p> <p>21 again, that doesn't matter out of the box. It's</p> <p>22 when it is implanted in the woman under load.</p> <p>23 Q. Yes. But those inflammatory cells</p> <p>24 don't just go in circles; do they, sir?</p> <p>25 A. Well, there's going to be</p>

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<p>1 literature -- and let's go to my expert report on  2 this, on degradation and pore size. I've got the  3 literature stated from individuals like Klinge,  4 Klosterhalfen, Costello, Clave, et al., who will  5 disagree with you, that, no, that pore size is  6 insufficient to have adequate tissue incorporation  7 and prevention of the inflammation which then  8 causes degradation, et cetera.  9 Q. Klinge and those doctors were  10 assessing hernia mesh, not the TVT device in the  11 application of stress incontinence in women;  12 correct?  13 MR. CARTMELL: Object to the form.  14 A. Okay. And then --  15 Q BY MR. SNELL: Is that a yes or no?  16 A. No. I can't answer a separate yes or  17 no because my understanding is they're doing  18 hernia meshes in the abdomen. TVT is a hernia  19 mesh being put into the vagina. So it's going to  20 be a worse of an environment because of higher  21 bacteria counts. Different types of strain. So  22 if it performs poorly in the abdomen, it's going  23 to perform worse in the vagina.  24 Q. All of the citations where you cite to  25 Klinge and those doctors in your report are in the</p>	<p>1 have been something very good for Ethicon to have  2 done.  3 MR. SNELL: Move to strike everything  4 up to the responsiveness about "when they" with  5 regard to TVT, no.  6 Q. BY MR. SNELL: You call him Klingel.  7 A. Klinge.  8 Q. Is it Klingel or Klinge? Because I  9 heard it all different ways.  10 MR. CARTMELL: I thought it's Klinge.  11 A. It's Klinge.  12 MR. CARTMELL: Klinge, okay. He said  13 Klinge.  14 Q BY MR. SNELL: Oh, I think he said  15 Klingel, like Chris Klingel? I just want to make  16 sure I know we're talking about the same person.  17 It's the same person; right?  18 A. Klinge, yeah.  19 Q. Okay. Look, I'm even worse than you  20 are with names, and you're pretty good with names.  21 I'm bad with them. All right.  22 MR. CARTMELL: Chris Klinge.  23 Q BY MR. SNELL: So we were looking at  24 that NICE guideline. It says down --  25 MR. CARTMELL: NICE or NICE.</p>
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<p>1 context of hernia; correct?  2 A. All right. Let's go to my expert  3 report on pore size, because if we're going to  4 talk about this in detail -- I spent a lot of time  5 on this, and so we can go to that. So I have it  6 down here beginning around page 18, where I  7 reference internal documents, studies, et cetera.  8 Q. None of them being TVT retropubic  9 device studies that were in women; correct?  10 A. Well, if --  11 Q. That's a yes or no. So which one is  12 it?  13 MR. CARTMELL: No. You can answer.  14 Let him answer. You cut him off again. That's  15 twice in the last minute and a half.  16 MR. SNELL: No, no. I can say a yes  17 or no question, Tom; you know that.  18 MR. CARTMELL: So let him answer the  19 question. Go ahead.  20 MR. SNELL: It's a yes or no.  21 MR. CARTMELL: Go ahead.  22 A. They have done studies looking at the  23 hernia mesh. Have Klinge, Klosterhalfen and  24 others done it specifically with the TVT? No.  25 But I have to extrapolate the data. That would</p>	<p>1 Q BY MR. SNELL: That's a good one.  2 It's abbreviated NICE.  3 A. I know it.  4 Q. All right. So for the NICE guideline  5 under colposuspension, it says, "Do not offer a  6 laparoscopic colposuspension as a routine  7 procedure for the treatment of stress UI in  8 women."  9 Do you see that?  10 A. Yes, I do.  11 Q. You've never done a laparoscopic  12 Burch; right?  13 A. No, I have not.  14 Q. Why would they say that respect to the  15 laparoscopic Burch?  16 A. Well, the laparoscopic Burch is really  17 not a -- let me start over.  18 A laparoscopic Burch is not a true  19 Burch procedure. They have to modify it, and it's  20 not really even a Burch. And the success has been  21 poor with the laparoscopic procedure called the  22 laparoscopic Burch.  23 Q. Under Biological slings they say, "Do  24 not offer anterior colporrhaphy, needle  25 suspensions, paravaginal defect repair and the MMK</p>

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<p style="text-align: right;">Page 170</p> <p>1 for the treatment of stress UI."</p> <p>2 Do you see that?</p> <p>3 A. Yes, I do.</p> <p>4 Q. Is that an accurate, up-to-date</p> <p>5 statement with regard to the practice of</p> <p>6 surgically treating female stress urinary</p> <p>7 incontinence?</p> <p>8 A. This is a very simplified, infantile</p> <p>9 form of it, but anterior colporrhaphy is to treat</p> <p>10 prolapses, not incontinence.</p> <p>11 Q. Okay.</p> <p>12 A. Needle suspensions have fallen out of</p> <p>13 favor because they don't work. Paravaginal defect</p> <p>14 repair, it's, again, a prolapse repair. It's not</p> <p>15 incontinence. MMK, in the correct the high-volume</p> <p>16 surgeon's hands can have decent success with it,</p> <p>17 but that's not everybody. So I agree that it's</p> <p>18 not going to be, by any means, for the</p> <p>19 overwhelming majority of people a first-line</p> <p>20 treatment.</p> <p>21 Q. Is the MMK taught at all to residents</p> <p>22 and fellows in Mayo?</p> <p>23 A. In the GYN department it may be, but</p> <p>24 not in urology at all.</p> <p>25 Q. Do you think it's a fair statement</p>	<p style="text-align: right;">Page 172</p> <p>1 Q. I printed this out September 18th,</p> <p>2 2015. You see that at the bottom?</p> <p>3 A. Yes.</p> <p>4 Q. This is where the Mayo Clinic is</p> <p>5 talking about urinary incontinence, particularly</p> <p>6 for women; right?</p> <p>7 A. Yes.</p> <p>8 Q. And you see on the second page, Mayo</p> <p>9 Clinic.</p> <p>10 And you still work at Mayo Clinic;</p> <p>11 right?</p> <p>12 A. Correct.</p> <p>13 Q. Talks about "Sling procedures to treat</p> <p>14 stress incontinence"; correct?</p> <p>15 A. Correct.</p> <p>16 Q. And they say Mayo Clinic -- are you</p> <p>17 employed by Mayo Clinic or are you an independent</p> <p>18 contractor?</p> <p>19 A. No. I'm employed by Mayo.</p> <p>20 Q. Mayo Clinic says sling procedures and</p> <p>21 bladder neck suspension procedures are the most</p> <p>22 common surgical procedures; right? Falling into</p> <p>23 those categories?</p> <p>24 A. I don't see where you're reading from.</p> <p>25 Q. Let me withdraw. Restate it.</p>
<p style="text-align: right;">Page 171</p> <p>1 that as between GYNs versus urologists, GYNs tend</p> <p>2 to do more colposuspension procedures than</p> <p>3 urologists, like yourself tend to favor slings</p> <p>4 more?</p> <p>5 MR. CARTMELL: Object to the form.</p> <p>6 A. Colposuspension just means a vaginal</p> <p>7 prolapse repair. So that's what you're talking</p> <p>8 about. They do more prolapse than we do?</p> <p>9 Q. BY MR. SNELL: No. They do more like</p> <p>10 Burch and MMK?</p> <p>11 A. Oh, yes. Oh, okay. I see what you're</p> <p>12 saying.</p> <p>13 That would probably be a fair</p> <p>14 statement, yes.</p> <p>15 (Recessed from 1:45 p.m. to</p> <p>16 1:50 p.m.)</p> <p>17 (Exhibit 16 marked.)</p> <p>18 Q. BY MR. SNELL: Doctor, I've handed you</p> <p>19 Exhibit 16. This is from the Mayo Clinic</p> <p>20 regarding urinary incontinence.</p> <p>21 Is this the information you had</p> <p>22 earlier referenced that Mayo puts out regarding</p> <p>23 urinary incontinence?</p> <p>24 A. Well, this is on their web site, yeah,</p> <p>25 which I had no role in this.</p>	<p style="text-align: right;">Page 173</p> <p>1 MR. CARTMELL: Where's it say that?</p> <p>2 Q. BY MR. SNELL: The topic under Sling</p> <p>3 procedures to treat stress incontinence on page 2.</p> <p>4 Are you there?</p> <p>5 A. Yes.</p> <p>6 Q. All right. And Mayo Clinic, your</p> <p>7 employer, says, "Most surgical procedures to treat</p> <p>8 stress incontinence fall into two main categories:</p> <p>9 Sling procedures and bladder neck suspension</p> <p>10 procedures."</p> <p>11 A. That's what it states, but the Mayo</p> <p>12 Clinic doesn't state anything. It's a building.</p> <p>13 So this is a writer that has been hired to do</p> <p>14 this, which I had no role in, but that's what they</p> <p>15 state there.</p> <p>16 Q. Well, Mayo Clinic doesn't put</p> <p>17 unreliable information on their web site to</p> <p>18 patients; do they?</p> <p>19 A. No. Again, I'm saying, Mayo Clinic is</p> <p>20 a building. So I'm saying it's like saying the</p> <p>21 White House said something. Well, no a person</p> <p>22 said it.</p> <p>23 But I'm saying, this is what is stated</p> <p>24 on the Mayo Clinic web site.</p> <p>25 Q. Right. And it says, "During a sling</p>

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<p>1 procedure, your surgeon uses strips of synthetic 2 mesh, your own tissue or sometimes animal or donor 3 tissue to create a sling or 'hammock' under your 4 urethra or bladder neck; correct?</p> <p>5 A. Correct.</p> <p>6 Q. And that's accurate; right?</p> <p>7 A. That is correct; yes.</p> <p>8 Q. Depending upon which option a surgeon 9 chooses to offer to his or her patients; correct?</p> <p>10 A. That's correct; yes.</p> <p>11 Q. "The sling procedure that's best for 12 you depends upon your individual situation," it 13 says.</p> <p>14 You'd agree with that?</p> <p>15 A. Correct.</p> <p>16 Q. It's got Tension-free sling under 17 that. You with me?</p> <p>18 A. Yes.</p> <p>19 Q. "No stitches are used to attach the 20 tension-free sling, which is made from a strip of 21 synthetic mesh tape"; correct?</p> <p>22 A. Correct.</p> <p>23 Q. And that's like the TVT retropubic 24 device; correct?</p> <p>25 A. That would be one of them, but there'd</p>	<p>1 material, infection and pain."</p> <p>2 That part I agree with. But in my 3 department, in Urology, no one uses meshes, except 4 for me one time in the past 2-1/2 years. I cannot 5 speak for the gynecologists. But I was not part 6 of writing this document.</p> <p>7 Q. So you disagree with the Mayo Clinic's 8 web site.</p> <p>9 MR. CARTMELL: Object to the form. He 10 has already answered that question. Okay? You 11 asked him specifically what the web site says. He 12 said he disagrees with it. So don't answer that.</p> <p>13 Q BY MR. SNELL: How about this? A 14 little further down it says, "A conventional sling 15 sometimes requires a larger incision than a 16 tension-free sling. You may need an overnight 17 stay in a hospital and usually a longer recovery 18 period. You may also need a temporary catheter 19 after surgery while you heal."</p> <p>20 You agree with that; right?</p> <p>21 A. Yes.</p> <p>22 Q. Do you teach your patients for whom 23 you do an autologous sling self-catheterization?</p> <p>24 A. No.</p> <p>25 Q. You had mentioned -- we were talking</p>
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<p>1 be a lot in that category, yes.</p> <p>2 Q. "Instead, body tissue holds the sling 3 in place"; correct?</p> <p>4 A. Correct.</p> <p>5 Q. "Eventually scar tissue forms in and 6 around the mesh to keep it from moving."</p> <p>7 That's correct?</p> <p>8 A. Yeah. That is part of the problem, 9 but, yes.</p> <p>10 Q. And then they talk about retropubic 11 and transobturator approaches that we've discussed 12 today; right?</p> <p>13 A. Correct.</p> <p>14 Q. Then on the next page, the Mayo Clinic 15 says, "Using surgical mesh is a safe and effective 16 way to treat stress urinary incontinence."</p> <p>17 A. That is what --</p> <p>18 Q. You agree with that; right?</p> <p>19 A. I disagree with that.</p> <p>20 Q. So you disagree with your employer, 21 the Mayo Clinic, that surgical mesh is a safe and 22 effective way to treat stress urinary 23 incontinence?</p> <p>24 A. And it says, "However, complications 25 can occur in some women, including erosion of the</p>	<p>1 about -- strike that.</p> <p>2 We were talking about the 17-year 3 paper by Nilsson, et al.?</p> <p>4 A. Correct.</p> <p>5 Q. And you had said you were not sure as 6 to whether that study followed patients who had 7 received the Prolene mesh?</p> <p>8 A. Oh, I said Arnaud was not sure, and so 9 subsequently I'm not sure.</p> <p>10 Q. I'm not asking about Arnaud. I'm 11 asking you.</p> <p>12 A. I was clarifying.</p> <p>13 Q. Okay. So what was your methodology in 14 selecting that one quote out of Arnaud's multiple 15 days of testimony?</p> <p>16 MR. CARTMELL: Object to the form. 17 I'm not sure what you mean.</p> <p>18 A. My methodology was, in this one very 19 straightforward. I read the deposition. They 20 asked Arnaud questions, is this TVT, and he says, 21 no, similar, but it is not TVT.</p> <p>22 They say, is this polypropylene 23 Ethicon, and he says, to the effect, no it could 24 be ours. It could be Bard's. I don't know. So 25 methodology on this one is straightforward.</p>

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<p>1 Q BY MR. SNELL: So you believe the</p> <p>2 testimony was in -- that he gave was in regards to</p> <p>3 the Nilsson study?</p> <p>4 A. In the original Ulmsten study that has</p> <p>5 subsequently been carried forward to 17 years.</p> <p>6 Q. Let's mark that.</p> <p>7 (Exhibit 17 marked.)</p> <p>8 Q BY MR. SNELL: You recognize this,</p> <p>9 Doctor, to be that same study we've been</p> <p>10 discussing by Nilsson, et al.?</p> <p>11 A. That is correct. That is a --</p> <p>12 MR. CARTMELL: The 17 year?</p> <p>13 A. That's what I'm trying to find out.</p> <p>14 MR. CARTMELL: This isn't the 17 year.</p> <p>15 This is 2000 --</p> <p>16 A. This is 2001.</p> <p>17 Q BY MR. SNELL: Right. This is the</p> <p>18 same study, but it reported that the mean</p> <p>19 follow-up of 56 months; right?</p> <p>20 A. Correct. I don't know what -- I don't</p> <p>21 see what the follow-up was on this one. Was it</p> <p>22 the 5 year?</p> <p>23 Q. It's right here. It's right here.</p> <p>24 Yeah. Yeah.</p> <p>25 A. It's the 5 year. Approximately 5 year</p>	<p>1 have read him say.</p> <p>2 Q. Right. The jury can ultimately hear</p> <p>3 testimony and decide whatever they want to.</p> <p>4 A. Correct.</p> <p>5 Q. But for you as a doctor, this is</p> <p>6 medical literature. Did you read this and ignore</p> <p>7 it or did you not know about this?</p> <p>8 A. Oh, I knew it. I knew it very well.</p> <p>9 I read all these, including the 17-year one. I</p> <p>10 also know that Ulmsten was paid \$400,000, which</p> <p>11 Arnaud said was a conflict of interest and would</p> <p>12 bias the results. I also know from other things</p> <p>13 that they don't necessarily write down what the</p> <p>14 truth is. All I know is the authors were getting</p> <p>15 paid \$400,000 originally and are getting money,</p> <p>16 save TVT. The medical director of Ethicon says, I</p> <p>17 don't know if it is, maybe not, but it's not TVT.</p> <p>18 Q. And you chose to go with the medical</p> <p>19 director?</p> <p>20 A. No, I'm keeping an open mind. I have</p> <p>21 to have data to show me clearly that this was.</p> <p>22 Because from my perspective from what Arnaud said,</p> <p>23 who should be the authority, this is a Mediscan</p> <p>24 product, and or possibly Bard mesh. So it raises</p> <p>25 a major problem for me. And I am not -- if you</p>
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<p>1 range. Yes.</p> <p>2 Q. Right.</p> <p>3 A. This is the 5-year study.</p> <p>4 Q. You're familiar with this. They</p> <p>5 follow the series at 5 years, 7, 11, and 17 years;</p> <p>6 correct?</p> <p>7 A. Yes, sir.</p> <p>8 Q. All right. And if you go to the</p> <p>9 Patients and Methods section, in the left column</p> <p>10 it says, "The TVT set consisted of two 6</p> <p>11 millimeter needles connected to a handle and a</p> <p>12 specific polypropylene (Prolene) mesh tape fixed</p> <p>13 to the needles."</p> <p>14 Do you see that?</p> <p>15 A. Yes, I do.</p> <p>16 Q. So this paper reports that the mesh</p> <p>17 they used in that Nilsson study was Prolene tape;</p> <p>18 correct?</p> <p>19 A. Even the medical director of Ethicon</p> <p>20 needs to get updated on his data. I don't know</p> <p>21 why he would raise those issues then, because he</p> <p>22 was there during this time frame and involved, as</p> <p>23 far as knowledge of these studies. So that would</p> <p>24 have to be answered by him. But he said it under</p> <p>25 oath. So all I'm doing is parroting back what I</p>	<p>1 show me -- if you have data to prove it, I would</p> <p>2 love to see it.</p> <p>3 Q. You mentioned the \$400,000 that</p> <p>4 Ulmsten received. Why does that matter to you?</p> <p>5 A. Well, conflict of interest and bias,</p> <p>6 unfortunately, exists in medicine. And that's why</p> <p>7 now we have to declare that. Originally we did</p> <p>8 not have to declare it. During my residency you</p> <p>9 didn't have to do it. Early on in staff, you</p> <p>10 didn't have to do it. But because of events like</p> <p>11 this, now you have to declare it.</p> <p>12 So if there is money and you stand to</p> <p>13 make a lot of money, there's the potential for</p> <p>14 bias. I didn't say there is there. I said</p> <p>15 there's a potential for it. There's clearly a</p> <p>16 conflict of interest, which Arnaud agreed with me</p> <p>17 on that. He said there is conflict of interest in</p> <p>18 this paper. So that is important. You have to</p> <p>19 read this article through that lens of potential</p> <p>20 bias.</p> <p>21 Q. And the same would hold true for all</p> <p>22 the Vypro and other studies you cited by</p> <p>23 Dr. Klinge who had a financial interest, correct,</p> <p>24 in promoting that product.</p> <p>25 A. You --</p>

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<p>1 MR. CARTMELL: Wait. Object to the 2 form. It's vague and ambiguous with respect to 3 what product you're talking about. 4 MR. SNELL: I said Vypro; didn't I? 5 Q. BY MR. SNELL: You know Dr. Klinge had 6 an interest in Vypro, don't you, Doctor? 7 A. I do know that. 8 Q. You know he's biased with regard to 9 Vypro; don't you? 10 A. No. There's a difference between 11 conflict of interest and bias. I am stating with 12 Nilsson and Ulmsten there is a conflict of 13 interest. There is the potential for bias. I 14 didn't say there was bias. And as a reviewer, I 15 have to keep an open mind and look at that. I'm 16 not denying at all with the Klinge, Klosterhalfen, 17 whichever one -- I can't remember which one's 18 which. But with Vypro, if there is a financial 19 interest there, that is a potential for conflict 20 of interest. If there is a conflict of interest, 21 potential for bias. 22 Q. All right. And you know for a fact 23 that exists with Dr. Klinge? 24 A. I don't know for a fact. I can't keep 25 track of who's got what where. But if you are</p>	<p>1 together. So that's not a fair comparison. The 2 Burch can be done -- you can get it done in a 5, 3 6, 7-centimeter incision. Outpatient, overnight 4 stay in the hospital. So, no, I disagree with 5 that. There are studies out there showing longer 6 stays. It's all over the board. 7 Q. But you'd at least agree with the 8 statement that the pubovaginal sling is effective 9 but is known to have a high rate of complications, 10 require long hospital stays, and patients often 11 experience a significant amount of pain? 12 MR. CARTMELL: Object to the form. 13 A. Again, we're looking at the 14 perioperative period. So I would agree with that, 15 but we have to always compare it to what. Are we 16 comparing it to TVT? Are we comparing it to the 17 synthetics? Are we comparing it to the MMK or 18 just any transabdominal procedure? 19 Q. BY MR. SNELL: You would agree with 20 the statement that mid-urethral sling procedures 21 are much less invasive than the earlier 22 pubovaginal sling procedures; right? 23 A. Overall, when you're doing a 24 comparison of synthetics to the pubovaginal or 25 Burch, those are -- the Burch and pubovaginal</p>
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<p>1 stating for me that he has a financial interest in 2 that, that does -- I have to be concerned about 3 that and look at it as objectively as I can. 4 Q. And you cited to Dr. Klinge more than 5 10 times in your expert report; right? 6 A. Probably. And I also cite the Nilsson 7 and Ulmsten studies quite a bit in there, too. 8 Those are all the body of evidence in the 9 methodology that I have to look at is look at the 10 potential for bias in papers. 11 Q. Tell me if you agree or disagree with 12 these assertions. The Burch and MMK are very 13 invasive, often result in complications, and 14 usually require prolonged hospital stays. 15 A. A lot of factors. It would be easier 16 if we go one by one or if you just want to -- if 17 you want to take the sentence in totality, it all 18 has to be true, I disagree with it. We can go bit 19 by bit through it, though. 20 Q. You would agree that Burch and MMK 21 both are very invasive? 22 A. I disagree. Compared to what? 23 Q. Compared to alternative surgeries for 24 stress urinary incontinence. 25 A. No. Now, you've lumped MMK and Burch</p>	<p>1 slings are going to be relatively more invasive. 2 Q. Would you agree or disagree with the 3 statement that tension-free mid-urethral sling, 4 like the TVT retropubic, is a significant 5 advancement in treating stress urinary 6 incontinence? 7 A. Oh, yes. And early on I was very -- 8 now, again, I never used the TVT because I was 9 described the various different fears of it. But 10 when TVT came out, it was revolutionary. It 11 changed the way we did things. But we didn't know 12 what we know now. And even comparing myself to 13 two or three years ago, my opinion has changed. 14 So, yeah, it was touted as being revolutionary. 15 (Discussion off the record.) 16 (Exhibit 18 marked.) 17 Q. BY MR. SNELL: Doctor, I've given you 18 the Cochrane Review. This is the publication in 19 2011. 20 A. Correct. 21 Q. You're familiar with this; correct? 22 A. Yes, I am. 23 Q. And this was the Cochrane Review where 24 they did a comparative analysis of like the 25 retropubic TVT versus the Burch or pubovaginal</p>

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<p>1 slings; correct?</p> <p>2 A. I see suburethral slings, open</p> <p>3 retropubic colposuspension. I don't see</p> <p>4 pubovaginal in there. I'm not saying it isn't</p> <p>5 there. I just don't see it.</p> <p>6 Q. Well, here, let's -- let me just --</p> <p>7 we'll go through it quickly. In the Results</p> <p>8 section -- I'm on the very front. They say,</p> <p>9 "Minimally invasive synthetic suburethral sling</p> <p>10 operations appeared to be as effective as</p> <p>11 traditional suburethral slings"; correct?</p> <p>12 A. Correct.</p> <p>13 Q. And when they talk about traditional</p> <p>14 suburethral slings, that would be like the</p> <p>15 autologous pubovaginal sling; correct?</p> <p>16 A. That's not nomenclature that's</p> <p>17 normally used. It's not called a suburethral</p> <p>18 sling. I would have to see what they're referring</p> <p>19 to. It's called a pubovaginal sling. It's not --</p> <p>20 suburethral slings, normal nomenclature is the</p> <p>21 synthetics.</p> <p>22 Q. On the next page where they go through</p> <p>23 the different procedures, they put the -- what I</p> <p>24 read to be the pubovaginal slings and the</p> <p>25 minimally invasive slings, like TVT, under the</p>	<p>1 recall seeing another meta-analysis. And, again,</p> <p>2 then I'd have to look at how long the follow-up</p> <p>3 is. Is it 12 months or is it 30 years. That's</p> <p>4 what matters to me, end of the patient.</p> <p>5 Q. "Minimally invasive synthetic slings</p> <p>6 appeared to be as effective as the open retropubic</p> <p>7 colposuspension."</p> <p>8 A. Yeah. I don't see where you are. And</p> <p>9 I wouldn't challenge --</p> <p>10 Q. I wouldn't mislead you. I'm just</p> <p>11 reading --</p> <p>12 A. No. I don't doubt. That's what we've</p> <p>13 been discussing all along. The Burch and the</p> <p>14 pubovaginal sling and the TVT have many studies</p> <p>15 showing they have similar efficacy.</p> <p>16 Q. And here's what I want to ask you</p> <p>17 about.</p> <p>18 But the TVT retropubic sling "has</p> <p>19 fewer perioperative complications, less</p> <p>20 postoperative voiding dysfunction, shorter</p> <p>21 operative time and hospital stay, but</p> <p>22 significantly more bladder perforations."</p> <p>23 A. Correct. And the key with that</p> <p>24 statement, as you read it, was perioperative. So</p> <p>25 that's immediate perioperative. And I'm not going</p>
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<p>1 category of suburethral slings.</p> <p>2 Do you see that?</p> <p>3 A. Yeah. What they're doing is they're</p> <p>4 comparing it to the colposuspension, which would</p> <p>5 be probably supra urethral slings -- or</p> <p>6 supra urethral suspension. That's probably what</p> <p>7 they're doing.</p> <p>8 Q. Okay. But they found that "the</p> <p>9 minimally invasive synthetic suburethral slings</p> <p>10 appeared to be as effective as the traditional</p> <p>11 suburethral slings, but with shorter operating</p> <p>12 time and less postoperative voiding dysfunction</p> <p>13 and de novo urgency symptoms; correct?</p> <p>14 A. Okay. That's what they state, yes.</p> <p>15 Q. And have you seen data consistent with</p> <p>16 that conclusion by this Cochrane Review?</p> <p>17 A. I've seen data consistent with it and</p> <p>18 inconsistent with it. So, again, I'd have to</p> <p>19 analyze each of the studies, what they're talking</p> <p>20 about.</p> <p>21 Q. Have you seen any other meta-analyses</p> <p>22 that report that for the TVT retropubic compared</p> <p>23 to pubovaginal slings, it has a higher rate of</p> <p>24 complications?</p> <p>25 A. Again, I'd have to see the -- I don't</p>	<p>1 to challenge. I think it's going to be somewhat</p> <p>2 of a relative issue. It's the long-term</p> <p>3 complications that I'm most concerned about and</p> <p>4 see on a daily basis in my clinic.</p> <p>5 Q. So in the comparative studies for like</p> <p>6 comparing to the Burch, there are some</p> <p>7 perioperative complications that appear to be</p> <p>8 higher with Burch as compared to the TVT; correct?</p> <p>9 A. Correct.</p> <p>10 Q. Bladder perforation being the one</p> <p>11 higher with the TVT because of the retropubic</p> <p>12 passage; correct?</p> <p>13 A. Correct.</p> <p>14 Q. A little further down they say that</p> <p>15 the "retropubic bottom-to-top route was more</p> <p>16 effective than the top-to-bottom route"; correct?</p> <p>17 A. That was their conclusion. It says</p> <p>18 effective in -- it doesn't say exactly here, but I</p> <p>19 assume they're talking about stress urinary</p> <p>20 incontinence. That's what they state.</p> <p>21 Q. That's consistent with the Ford paper</p> <p>22 you cited; right?</p> <p>23 A. Yes.</p> <p>24 Q. And the approach used by TVT</p> <p>25 retropubic "incurred significantly less voiding</p>

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<p style="text-align: right;">Page 190</p> <p>1 dysfunction, bladder perforations, and tape 2 erosions"; correct? 3 A. That's what they state, yes. 4 Q. That's consistent with the Ford paper; 5 right? 6 A. I'd have to look back at that, but it 7 sounds similar. 8 Q. "Monofilament tapes had significantly 9 higher objective cure rates compared to 10 multifilament tapes and fewer tape erosions." 11 Do you see that? 12 A. Yes. 13 Q. And TVT is a monofilament tape; 14 correct? 15 A. Correct. 16 Q. And that's a benefit of monofilament 17 tapes over multifilament tapes, where they have 18 fewer erosions; correct? 19 A. Yeah. The multifilament is going to 20 be a worse product. Doesn't mean monofilament is 21 safe. It just says is safer relative to the worst 22 product. Worse -- 23 Q. And the -- I'm sorry. You're going -- 24 A. No, no, no, no. 25 Q. And the monofilament tape had a rate</p>	<p style="text-align: right;">Page 192</p> <p>1 Let's see here. There's Kuhn, et al. 2 Q. Let me see where you're at. 3 A. Which is a TVT paper. Let me see 4 where Kuhn is referenced. I'd have to search for 5 it. 6 Q. Just so I'm on the same page as you, 7 Doctor, I appreciate you telling me what page of 8 your report you're on where you discuss 9 contraction with the TVT. I'm going to let you -- 10 let's take a quick break. 11 (Recessed from 2:17 p.m. to 12 2:28 p.m.) 13 Q BY MR. SNELL: All right. Okay, 14 Doctor, before we took a break, I asked you to 15 show me in your expert report where you discuss 16 contraction rates with regard to the TVT device 17 and its use in women for stress urinary 18 incontinence. 19 Can you point me to that? 20 A. Well, in the Contraction section, 21 obviously we do a lot of discussion about 22 contraction, various different studies with it. 23 When we limit it specifically to TVT, I think we 24 have to look at Wang, et al., on page 24, where 25 we're talking about infections, erosions and</p>
<p style="text-align: right;">Page 191</p> <p>1 of erosion of 1.3 percent; correct? 2 A. Based upon their analysis here in the 3 hands of experts and short-term follow-up, yes, 4 that's the number they found. 5 Q. Were you aware of this Ogah/Cochrane 6 Review at the time you wrote your draft -- your 7 expert report? 8 A. I don't recall when I became aware of 9 it. It's a -- it's a well-known paper. 10 Q. In looking at your report, I did not 11 see you citing to any TVT retropubic device 12 literature where the device had been used to treat 13 stress urinary incontinence in women and where it 14 was reported that there was contraction. 15 Is that a fair statement with regard 16 to your report? 17 A. No. That would be incorrect. 18 Q. Where in your report do you report 19 studies in TVT in women that reports contractions? 20 A. Well, wherever there is pain, wherever 21 there is extrusion, that is evidence of 22 contraction. 23 Q. Where in your report do you report 24 that? 25 A. Well, if we go to pain or dyspareunia.</p>	<p style="text-align: right;">Page 193</p> <p>1 exposures, because the complication of contraction 2 is intimately tied to also exposures and 3 infections. 4 Q. So TVT and contraction -- strike that. 5 So for TVT contraction in women, you 6 point me to Wang on page 24? 7 A. That's when you specifically limit it 8 just to the TVT product. 9 Q. Right. 10 A. Because as I mentioned, all 11 complications are all intertwined. So exposure, 12 infection is intertwined with inflammation, 13 contraction, degradation, et cetera. 14 Q. And the other part of your report 15 where you talk about contraction, you talk about 16 Klinge and his discussion of hernia mesh 17 contraction; right? 18 A. That is correct, because that is a TVT 19 mesh implanted via the abdominal route. 20 Q. All right. It's not cut to and 21 configured as TVT is; correct? 22 A. No. But without -- no, you are 23 correct. However, the TVT mesh has different 24 forces placed upon it that the hernia meshes do 25 not, i.e., you can make hernia meshes lay flat.</p>



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<p style="text-align: right;">Page 194</p> <p>1 You can't do that with the vagina.</p> <p>2 Q. The hernia mesh does not have a sheath</p> <p>3 on it; correct?</p> <p>4 A. No. It does not, but it's also not</p> <p>5 placed in the vagina to have bacterial</p> <p>6 contamination.</p> <p>7 Q. When you say bacterial contamination,</p> <p>8 you're not referring to infection; are you?</p> <p>9 A. I'm referring to bacterial</p> <p>10 contamination.</p> <p>11 Q. Right. There is a difference between</p> <p>12 bacterial contamination and infection; correct?</p> <p>13 A. Yes, but infection starts with a</p> <p>14 contamination.</p> <p>15 Q. Right. You're aware of the paper by</p> <p>16 Pat Culligan where they found and they quantified</p> <p>17 the different bacteria counts in the vagina?</p> <p>18 A. Correct.</p> <p>19 Q. In that study there were patients who</p> <p>20 received the TVT as well; correct?</p> <p>21 A. I'd have to look at it. I don't</p> <p>22 recall the specifics.</p> <p>23 Q. Would it surprise you to learn that</p> <p>24 there were no infections with the TVT mesh in the</p> <p>25 Culligan paper.</p>	<p style="text-align: right;">Page 196</p> <p>1 Q. And you have not stated in your report</p> <p>2 the rate at which clinical infections occur with</p> <p>3 TVT; have you?</p> <p>4 A. I don't recall that specific, but the</p> <p>5 way you phrase it, specifically mentioned in</p> <p>6 there.</p> <p>7 Q. I have not seen in your expert report</p> <p>8 where you calculate and state the complication</p> <p>9 rates with the TVT retropubic device.</p> <p>10 A. Because we don't know the true</p> <p>11 complication rate. We can quote studies, as I</p> <p>12 mentioned, in high volume surgeons with limited</p> <p>13 follow-up. We can quote those. But as I said, we</p> <p>14 don't know the true complication rate.</p> <p>15 Q. Well, there are meta-analyses, and</p> <p>16 we've gone through a couple of them today and</p> <p>17 various other studies that report rates of</p> <p>18 complications, and you're aware of that; correct?</p> <p>19 A. Yes. But that does not reflect what</p> <p>20 is happening out in the real world and what I see</p> <p>21 in my daily practice. That the average low-volume</p> <p>22 surgeon, who does the majority of the TVTs in the</p> <p>23 United States, that's what -- you know, because</p> <p>24 Arnaud even admitted, their complication rates are</p> <p>25 even going to be higher. So, yes, we can quote</p>
<p style="text-align: right;">Page 195</p> <p>1 MR. CARTMELL: Object to the form.</p> <p>2 A. I would have to look at the</p> <p>3 methodology, because methodology is very</p> <p>4 important. I'd have to look at how they did the</p> <p>5 study and what they looked at.</p> <p>6 Q BY MR. SNELL: Have you looked at</p> <p>7 that?</p> <p>8 A. Yes, I have, but I don't have it off</p> <p>9 the top of my head.</p> <p>10 Q. Is it your opinion that whenever mesh</p> <p>11 is placed through the vagina there is bacteria</p> <p>12 that gets on it?</p> <p>13 A. We know that the vagina's impossible</p> <p>14 to sterilize, and so when you place it through the</p> <p>15 vagina, you are going to have contact with that.</p> <p>16 So it's even with the sheath on it, but then when</p> <p>17 you remove the sheath, there's going to be issues</p> <p>18 there. So the risk for contamination on every</p> <p>19 single one is definitely there.</p> <p>20 Q. But that does not translate into</p> <p>21 infection?</p> <p>22 A. It might not translate into a clinical</p> <p>23 infection/abscess, but it can correlate to a</p> <p>24 subclinical infection, leading to inflammation,</p> <p>25 degradation, and that cascade.</p>	<p style="text-align: right;">Page 197</p> <p>1 extensively the studies that you've done that show</p> <p>2 these various different complication rates with</p> <p>3 short-term follow-up and highly experienced</p> <p>4 surgeons.</p> <p>5 Q. In the studies that report on the TVT</p> <p>6 retropubic device, what percentage of those</p> <p>7 studies involved surgeons who were of average</p> <p>8 quality?</p> <p>9 A. Well, I can't speak to quality. All</p> <p>10 we can speak to is volume.</p> <p>11 Q. How many of those then had average</p> <p>12 volume for the TVT retropubic studies?</p> <p>13 A. Most likely very few of those had</p> <p>14 small volume. And the Kuuva study, they</p> <p>15 eliminated the lower volume studies -- lower</p> <p>16 volume people. So they falsely raised their</p> <p>17 success rate and lowered their complication rate.</p> <p>18 But, no, small volume surgeons aren't going to</p> <p>19 publish anything because they're small volume.</p> <p>20 MR. SNELL: Move to strike.</p> <p>21 Q. BY MR. SNELL: Do you know of all the</p> <p>22 TVT retropubic device studies which percent of</p> <p>23 them included surgeons that had average volume or</p> <p>24 less?</p> <p>25 MR. CARTMELL: Object to the form.</p>

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<p>1 Asked and answered. He said a very small 2 percentage of those. He answered your question. 3 He also said other information, but he 4 specifically answered your question. So please 5 move on.</p> <p>6 Q BY MR. SNELL: Is that correct; you 7 believe it's a very small number?</p> <p>8 A. Average or low-volume surgeons aren't 9 going to have their data included because they 10 don't have enough data to analyze.</p> <p>11 The only way I can answer your 12 question is Kuuva, et al., where they actually 13 eliminated the small volume surgeons who had done 14 less than 15.</p> <p>15 Q. I'm familiar with the Kuuva paper. 16 I'm talking about the hundreds of other TVT 17 retropubic papers. In those, is it correct that 18 you don't know what percent of those papers 19 reported on surgeons who had average to low 20 volume?</p> <p>21 MR. CARTMELL: Objection. Asked and 22 answered. You can tell him again.</p> <p>23 A. As I stated, my opinion is it's going 24 to be a very, very small number of small volume 25 surgeons are going to be included in those</p>	<p>1 analysis by which you segregated the investigators 2 who had low to average surgical volume as compared 3 to more than that?</p> <p>4 A. I have reviewed the literature 5 extensively. Can I quote to a certain specific 6 paper? No. If you have one, show me, and I'll 7 keep an open mind and modify my statement. But 8 this is based upon experience. Again, national, 9 international meetings. Editor -- or reviewer of 10 15 different journals. And I'm reading these 11 papers constantly. And you're not seeing 12 low-volume surgeons produce papers. The only one 13 that comes close to it is Anger, et al., which 14 demonstrated that low-volume surgeons had higher 15 complication rates.</p> <p>16 Q. Do you believe lower-volume surgeons 17 with other stress incontinence surgeries, like the 18 Burch or pubovaginal slings, have higher 19 complication rates?</p> <p>20 A. I would think that would be true. And 21 those surgeons usually don't do those surgeries 22 because they are more complicated surgeries to 23 perform. It takes more talent to do. So most of 24 those surgeons don't do it. That was the 25 revolutionary aspect of TVT because it opened up</p>
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<p>1 studies, if any, because you don't write up a 2 paper if you've done 10. No one's going to get 3 accepted.</p> <p>4 Q BY MR. SNELL: Well, you wrote up a 5 paper where you did 10 transobturator procedures?</p> <p>6 A. Absolutely I did, and that was called 7 a feasibility study. In properly counseled 8 patients. I am not out there touting that that is 9 the new gold standard. That's why we called it a 10 feasibility study.</p> <p>11 Q. Other than the Kuuva paper, what are 12 you relying on for that statement that it would be 13 a very, very small number?</p> <p>14 A. Based upon my experience and 15 attendance at national and international meetings, 16 working at a tertiary care center, working on the 17 journal articles from 15 different journals, that 18 small volume surgeons don't write papers because 19 there's nothing there to publish. So, therefore, 20 my experience is, and I'll state unequivocally, 21 very, very small percentage. If you want a 22 number, 1 to 2 percent, if that. And they're not 23 going to get published anywhere.</p> <p>24 Q. Have you surveyed the literature for 25 all the TVT retropubic device studies and done an</p>	<p>1 minimal -- it opened up stress incontinence 2 surgery to the common surgeon.</p> <p>3 Q. Is the common surgeon unqualified in 4 your opinion to do TVTs?</p> <p>5 A. The common surgeon needs to -- no, the 6 common surgeon -- let's be careful on the word 7 "common." I'm saying the average, private 8 practice surgeon, who is doing less than 15 or so 9 a year, based upon the Kuuva study, et al., is 10 going to be having a higher complication rate. 11 Most of these studies also demonstrate in highly 12 experienced hands.</p> <p>13 So I'm saying as far as the common, 14 the average surgeon out there, they are not going 15 to have the expertise of the high-volume surgeons; 16 hence, complications go up.</p> <p>17 Q. Do you believe that surgeons in 18 private practice have less surgical skills than 19 surgeons in universities?</p> <p>20 A. Absolutely not. It just depends upon 21 their experience. There are some that I know in 22 private practice who do very high volumes. It's 23 not an issue of the specific individual. It's an 24 issue of their volumes. And you know if you look 25 at the Nilsson study, Nilsson is a five-year</p>

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<p>1 study. That was -- five-year study? Yeah. It's</p> <p>2 a five-year study.</p> <p>3 See, they very clearly -- all surgeons</p> <p>4 involved were experienced urogynecologists well</p> <p>5 trained in TVT surgery. That's not going to be</p> <p>6 your average surgeon. That's are highly qualified</p> <p>7 people.</p> <p>8 Q. How many average pelvic surgeons in</p> <p>9 the United States use TVT?</p> <p>10 A. I can't answer that question. I don't</p> <p>11 know the -- a way of referencing it. We'd have to</p> <p>12 look at ethical sales and where they go to and the</p> <p>13 volumes that move off the shelf. That data would</p> <p>14 be available.</p> <p>15 Q. Have you analyzed that data?</p> <p>16 A. That data's been tried to get and</p> <p>17 can't.</p> <p>18 Q. How many high-volume surgeons are</p> <p>19 there in the United States for TVT retropubic</p> <p>20 device as you define high volume?</p> <p>21 A. There's going to be a certain number.</p> <p>22 But I don't know what that number would be.</p> <p>23 Around the nation there's going to be people that</p> <p>24 are going to be very good surgeons.</p> <p>25 Q. Are residents -- do residents</p>	<p>1 insufficient.</p> <p>2 Q. Have you analyzed the studies overall</p> <p>3 that show that the majority of complications do</p> <p>4 occur in the first 12 months?</p> <p>5 MR. CARTMELL: Object to the form. I</p> <p>6 think it misstates the evidence in the studies.</p> <p>7 A. Yeah. And it's also -- the</p> <p>8 complications they know of at that point. Because</p> <p>9 I can give you examples of bladder erosions that</p> <p>10 I've taken care of that I put in the sling that at</p> <p>11 7 years they're fine. At year 8 there's an</p> <p>12 erosion, which we've examined. So we have to look</p> <p>13 at the life of the patient.</p> <p>14 Q BY MR. SNELL: In the studies that</p> <p>15 report on TVT retropubic at five years duration or</p> <p>16 more, what is the rate of mesh exposure occurring</p> <p>17 after five years.</p> <p>18 A. It's unknown.</p> <p>19 Q. You mentioned the Wang paper. Let me</p> <p>20 just make sure I have it here. I think I do.</p> <p>21 (Exhibit 19 marked.)</p> <p>22 Q. BY MR. SNELL: Is this the Wang paper</p> <p>23 you referenced, Doctor, with regard to TVT?</p> <p>24 A. Correct. 2004 publication, yes.</p> <p>25 Q. And that paper says on the first page</p>
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<p>1 typically have higher complication rates than the,</p> <p>2 you know, professors or the surgeons who teach</p> <p>3 them?</p> <p>4 A. It depends. If the resident is</p> <p>5 running solo and doing a case without any</p> <p>6 supervision, that possibly could be the case.</p> <p>7 However, if they have been well trained in a</p> <p>8 certain procedure and they're doing it solo and</p> <p>9 they've done more than anybody else -- they've</p> <p>10 done an acceptable number, their complications are</p> <p>11 going to be low. There's too many variables to be</p> <p>12 able to answer that question.</p> <p>13 Q. If a surgeon is a -- strike that.</p> <p>14 If a surgeon is more than an average</p> <p>15 surgeon, as you've stated, and he or she uses TVT</p> <p>16 retropubic device, based upon the data, you would</p> <p>17 agree then that the rate of complications are</p> <p>18 acceptable in his or her hands?</p> <p>19 A. Number one, acceptable, no. Number</p> <p>20 two, it depends upon what -- how much follow-up</p> <p>21 they have. And it's true, a surgeon can put in</p> <p>22 the device and at one year that woman has not</p> <p>23 experienced any complications yet. But that</p> <p>24 device is going to stay in her the rest of her</p> <p>25 life. That's why I'm saying all these studies are</p>	<p>1 "Prolene tape seems unusually biocompatible when</p> <p>2 used as a suburethral sling"; correct?</p> <p>3 It's all on the very first page.</p> <p>4 A. I'm sorry. Where are you?</p> <p>5 Q. Very first page. Right here.</p> <p>6 A. That's what it states, yes.</p> <p>7 Q. And so this paper by Wang is actually</p> <p>8 inconsistent with your belief that Prolene --</p> <p>9 strike that.</p> <p>10 Do you believe Prolene mesh is not</p> <p>11 biocompatible?</p> <p>12 A. I do not believe it is biocompatible,</p> <p>13 no.</p> <p>14 Q. In what percentage of patients is</p> <p>15 Prolene tape -- strike that.</p> <p>16 In what percentage of patients is the</p> <p>17 Prolene mesh used in TVT for the treatment of</p> <p>18 incontinence not biocompatible?</p> <p>19 A. That's impossible to know because</p> <p>20 there's been no good studies looking long-term at</p> <p>21 them.</p> <p>22 Q. Well, in this paper, out of 700 women</p> <p>23 that you reference, the rate of exposure was</p> <p>24 2.4 percent; correct?</p> <p>25 MR. CARTMELL: Object to the form.</p>

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<p>1 A. Correct. During the time period of</p> <p>2 this study, of 7 -- I don't see what the follow-up</p> <p>3 is.</p> <p>4 MR. CARTMELL: I think that misstates</p> <p>5 the evidence. The question assumes facts that are</p> <p>6 not in evidence.</p> <p>7 A. The paper, at least in the abstract,</p> <p>8 does not state the follow-up time. But this paper</p> <p>9 states defective vaginal healing that became</p> <p>10 clinically significant was 2.4 percent during the</p> <p>11 study period. But, again, I'm trying to find</p> <p>12 the -- this is at 1 to 3 months. Defective</p> <p>13 healing from 1 to 3 months, it looks like. So</p> <p>14 it's a very short-term study.</p> <p>15 Q BY MR. SNELL: Well, they actually</p> <p>16 looked at a longer time period than 3 months in</p> <p>17 this paper; right? It's just that the healing</p> <p>18 problems arose before three months; correct?</p> <p>19 A. The acute healing problems arose</p> <p>20 during that time, yes.</p> <p>21 Q. And so that means that 97.6 percent of</p> <p>22 the women did not have vaginal healing problems;</p> <p>23 right?</p> <p>24 A. At the time the study was conducted.</p> <p>25 Q. Fair enough.</p>	<p>1 complained of pain, 4 complained of dyspareunia, 5</p> <p>2 complained of vaginal bleeding and irritated</p> <p>3 voiding. And so to break it down into specific</p> <p>4 little complications is disingenuous at best. But</p> <p>5 going to that, yeah, 4 out of 700 complained</p> <p>6 specifically of dyspareunia during this short</p> <p>7 period of time, short period of follow-up.</p> <p>8 Q. And that's less than 1 percent; right?</p> <p>9 A. It's whatever the math is. Again, I</p> <p>10 don't -- I can trust you on the math, I think.</p> <p>11 Q. 5 out of 700's less than 1 percent;</p> <p>12 correct?</p> <p>13 MR. CARTMELL: He's answered you.</p> <p>14 Asked and answered.</p> <p>15 Q. BY MR. SNELL: I'm talking about the</p> <p>16 pain rate now. Not dyspareunia.</p> <p>17 A. Pain? Well, pain -- if you want pain,</p> <p>18 it's going to be different. So it's going to be</p> <p>19 9. Pain is roughly a 2 percent incidence of pain</p> <p>20 at that point in time.</p> <p>21 Q. Where do you get 2 percent?</p> <p>22 A. We have five women complained of pain.</p> <p>23 Four women complained of dyspareunia. Five women</p> <p>24 complained of vaginal bleeding and irritated</p> <p>25 voiding.</p>
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<p>1 And you see there were four women what</p> <p>2 complained of dyspareunia? I'm right here in the</p> <p>3 Results section.</p> <p>4 A. Five complained of pain and four</p> <p>5 complained of dyspareunia by themselves or their</p> <p>6 partner.</p> <p>7 Q. And so four women complained of</p> <p>8 dyspareunia by themselves or their partner or</p> <p>9 partner discomfort; right?</p> <p>10 A. Yes. So nine patients overall</p> <p>11 complained of pain.</p> <p>12 Q. All right.</p> <p>13 A. Four complained of dyspareunia.</p> <p>14 Q. And as for dyspareunia, that rate is</p> <p>15 0.57 percent; correct? This paper you point to.</p> <p>16 A. A -- well, it's 4 out of 700 patients</p> <p>17 at that short-term follow-up. That's how many</p> <p>18 complained of dyspareunia.</p> <p>19 Q. And does it sound about right that</p> <p>20 that rate is 0.57 percent.</p> <p>21 A. I would have to do the math on it.</p> <p>22 I'll have to take your word for that.</p> <p>23 Q. Well, 4 is certainly -- 4 women out of</p> <p>24 700 is certainly less than 1 percent; right?</p> <p>25 A. Well, if you look at this, 5 women</p>	<p>1 Q. Doesn't say those five complained of</p> <p>2 pain.</p> <p>3 A. No, they didn't. But they</p> <p>4 complained -- they complained of something else.</p> <p>5 So, again, what is always -- I'll let you have</p> <p>6 this, but as a doctor that takes care of patients</p> <p>7 who are crying in my office, you guys break down</p> <p>8 the complications. Yeah. So, yes. 9 patients in</p> <p>9 this series out of 700 complained of pain. The</p> <p>10 other ones weren't happy with vaginal bleeding,</p> <p>11 irritated voiding.</p> <p>12 Q. That was five who weren't happy with</p> <p>13 vaginal bleeding or irritated voiding; correct?</p> <p>14 A. Correct.</p> <p>15 Q. And they ended up, 7 patients in this</p> <p>16 series that you point to required excision of the</p> <p>17 exposed suburethral part of the sling; is that</p> <p>18 correct?</p> <p>19 A. That's correct.</p> <p>20 Q. So that was an excision rate of only</p> <p>21 1 percent in this entire cohort; right?</p> <p>22 A. During the very limited follow-up</p> <p>23 duration of this study, that is the number they</p> <p>24 came up with.</p> <p>25 Q. When you say limited follow-up</p>

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<p>1 duration, why do you say that?</p> <p>2 A. What's going to happen in 5 years? 10</p> <p>3 years? 20 years?</p> <p>4 Q. How about this? Why don't we look a</p> <p>5 little bit further below that. You see the mean</p> <p>6 follow-up of 68.2 months?</p> <p>7 A. Okay. What about 69 months -- I'm</p> <p>8 sorry.</p> <p>9 Q. That's over five years, isn't it,</p> <p>10 Doctor?</p> <p>11 A. And as I have mentioned over and over</p> <p>12 and over, this is an implantable medical device,</p> <p>13 as you mentioned. There are studies out there.</p> <p>14 Klinge, 15 years, degradation continues. This is</p> <p>15 a progressive process. I see these patients in my</p> <p>16 clinic that aren't being followed by anybody. So</p> <p>17 I'm saying 5 years, that's a step in the right</p> <p>18 direction. But if a woman lives 30 years beyond</p> <p>19 that, what's going to happen in that time frame?</p> <p>20 Our data suggests it's going to get worse.</p> <p>21 MR. SNELL: Move to strike.</p> <p>22 Q. BY MR. SNELL: In this paper you point</p> <p>23 to -- you pointed me to, at over 5 years</p> <p>24 follow-up, there was only 1 percent rate of mesh</p> <p>25 excision to treat the exposure; right?</p>	<p>1 MR. SNELL: You're not testifying,</p> <p>2 Tom, please.</p> <p>3 MR. CARTMELL: -- there's 7 erosions</p> <p>4 when there's 17 erosions. In fairness.</p> <p>5 MR. SNELL: You know what. You're</p> <p>6 totally off base.</p> <p>7 MR. CARTMELL: I am?</p> <p>8 MR. SNELL: Yes.</p> <p>9 MR. CARTMELL: Tell me how.</p> <p>10 MR. SNELL: On your time I was asking</p> <p>11 him about erosions that needed surgical -- where's</p> <p>12 the paper? We just went through this, didn't we,</p> <p>13 Doctor.</p> <p>14 MR. CARTMELL: 17 erosions. 17</p> <p>15 erosions, it says right here.</p> <p>16 MR. SNELL: Tom, you're being</p> <p>17 nonsensical. I asked him about the ones that</p> <p>18 required excision.</p> <p>19 MR. CARTMELL: No, you didn't. You</p> <p>20 said erosions in general, and the record will</p> <p>21 reflect that.</p> <p>22 Q. BY MR. SNELL: Sir, don't you remember</p> <p>23 me asking you about 7 of those patients required</p> <p>24 excision of the exposed suburethral part of the</p> <p>25 sling? Didn't I ask you about that?</p>
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<p>1 A. That is what the study stated at five</p> <p>2 years, yes.</p> <p>3 Q. So that means at a mean follow-up</p> <p>4 greater than 5 years, 99 percent of the women in</p> <p>5 this entire large cohort didn't need a mesh</p> <p>6 excision procedure; correct?</p> <p>7 A. The key is yet.</p> <p>8 Q. And there are other studies that</p> <p>9 report --</p> <p>10 MR. CARTMELL: Just for the record, I</p> <p>11 want it to be clear, because I think it's unfair</p> <p>12 to the witness that you've been representing that</p> <p>13 there was a small number of erosions. And I think</p> <p>14 there were 17 erosions in the cohort. And I want</p> <p>15 the record to be clear for that.</p> <p>16 MR. SNELL: I think -- the study says</p> <p>17 what it says, so I can't --</p> <p>18 MR. CARTMELL: Yeah, but you're just</p> <p>19 kind of trying to trick him, you know, because</p> <p>20 you --</p> <p>21 MR. SNELL: I'm not tricking him. He</p> <p>22 pointed to this study, Tom. He knows this study.</p> <p>23 Don't try to tell me I'm tricking a witness about</p> <p>24 a paper he told me -- he's pointing me to.</p> <p>25 MR. CARTMELL: So don't say --</p>	<p>1 A. You asked me a question. I can't</p> <p>2 remember the specific details of it.</p> <p>3 Q. BY MR. SNELL: But it says seven</p> <p>4 required excision of the exposed suburethral part</p> <p>5 of the sling; right?</p> <p>6 A. That's what that says there, and the</p> <p>7 other part says 17 out of 100 had defective</p> <p>8 vaginal healing.</p> <p>9 Q. And it gives the measurement, CA 1</p> <p>10 times 0.5 centimeters; correct?</p> <p>11 MR. CARTMELL: Okay. Now, it's all on</p> <p>12 the record. Now it's fair.</p> <p>13 MR. SNELL: It was fair before. He</p> <p>14 cited to the document. He knows the study.</p> <p>15 (Exhibit 20 marked.)</p> <p>16 Q. BY MR. SNELL: Giving you one of the</p> <p>17 publications by Klinge, Alloplastic Implants for</p> <p>18 the Treatment of Stress Urinary Incontinence and</p> <p>19 Pelvic Organ Prolapse.</p> <p>20 You see this?</p> <p>21 A. Yes, I do.</p> <p>22 Q. Whereas you cited to Klinge about</p> <p>23 hernia and other papers, you didn't cite to his</p> <p>24 discussion of the TVT mesh; did you?</p> <p>25 A. I don't recall that specifically.</p>

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<p>1 Q. Look for where Klinge was writing 2 about meshes in stress urinary incontinence. 3 You there? 4 A. Yes. I mean, I'm sorry. I'm at the 5 Meshes and Stress Urinary Incontinence. I'm there 6 now. 7 Q. All right. And you saw Dr. Klinge was 8 one of the authors of this section; right? 9 A. Correct. 10 Q. And it says, "At present the gold 11 standard in SUI surgery is the suburethral sling 12 using either the tension-free vaginal tape (TVT) 13 or the transobturator tape (TOT) technique"; 14 correct? 15 A. That's what he states, yes. 16 Q. And do you disagree with Dr. Klinge? 17 A. I disagree. 18 Q. It said, the initial concern that the 19 meshes used might lead to high rates of erosions, 20 did not hold true when macroporous polypropylene 21 was used; correct? 22 A. That's what it states, yes. 23 Q. And here when Dr. Klinge is talking 24 about macroporous polypropylene in the context of 25 stress urinary incontinence, he's talking about</p>	<p>1 referencing to the Meschia study. 2 Q. And you know that that's a study that 3 looks at the Ethicon TVT retropubic device? 4 A. I'd have to look back at the study. I 5 don't remember the study. 6 Q. Okay. So at least in the context of 7 the intended use to treat stress urinary 8 incontinence with regard to the TVT device, he 9 reports that tape is a type 1 macroporous tape? 10 A. That's what he reports in 2010. 11 Q. Right. 12 A. Which then reflects data from 2008. 13 And that's what he states. 14 I disagree with it. Be interesting to 15 what he says now. 16 Q. Now that he's been paid hundreds of 17 thousands of dollars by the plaintiffs' lawyers in 18 the mesh litigation? 19 MR. CARTMELL: Object to the form. 20 It's argumentative. Be distracting. 21 A. If you want to go on the record that 22 he's being biased. 23 Q. BY MR. SNELL: Do you know how many 24 royalties he -- Dr. Klinge received on Vypro? 25 A. I'm not familiar with that number</p>
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<p>1 the mesh in TVT; correct? 2 MR. CARTMELL: Object to the form. 3 A. No. He doesn't state which he's 4 talking -- referring to. The sentence prior, it 5 says TVT or transobturator tape. There's a lot of 6 different ones out there. And then he says, "The 7 initial concern that meshes." He does not say 8 TVT. So all he's saying is meshes. 9 Q. BY MR. SNELL: Well, you see below 10 that, right, where he talks about -- he follows up 11 on his point. 12 He says, "There was a zero percent 13 exposure rate using the classical TVT (Type 1 14 macroporous monofilament polypropylene) mesh in 15 the same trial"; correct? 16 A. Well, that's in the second -- in the 17 next paragraph down. I'm talking about the 18 sentence you showed me. Initial concern that 19 meshes. So it doesn't say TVT. We can agree it 20 says meshes, and I'll agree that's what it states, 21 but he doesn't say TVT. 22 Q. We can agree that he says the 23 classical TVT (type 1 macroporous monofilament 24 polypropylene) mesh; right? 25 A. That's what he's saying when he's</p>	<p>1 because I'm doing involvement of TVT case, not 2 Vypro. 3 Q. Do you know how many royalties 4 Dr. Klinge has received for ULTRAPRO? 5 A. The same answer as before, because I 6 know what data I've been provided on TVT. I have 7 not been provided confidential data on Vypro or 8 the other ones. 9 Q. And you don't disagree that when Amid 10 type 3 mesh, used for intravaginal slingplasty, 11 the vaginal erosion rate was 9 percent, and the 12 rate was 0 percent with TVT? 13 MR. CARTMELL: Object to the form. 14 A. I agree with the first part. I don't 15 agree with the second part. 16 The Amid type 3 like the ObTape, which 17 I'm very familiar with, had an unacceptably 18 significant complication rate with it. 19 Q. BY MR. SNELL: And you didn't cite to 20 this writing by Klinge in your expert report; did 21 you? 22 A. I cited Klinge multiple times. I 23 don't know if this specific -- this is a book 24 chapter. I quoted this one. Book chapters I tend 25 not to quote.</p>

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<p>1 Q. Well, this is one place in the medical</p> <p>2 literature where Dr. Klinge discussed his views on</p> <p>3 what type of mesh TVT mesh was in the application</p> <p>4 of treating stress urinary incontinence and</p> <p>5 whether or not it was the gold standard.</p> <p>6 Have you seen that published anywhere</p> <p>7 else?</p> <p>8 MR. CARTMELL: Objection.</p> <p>9 Q BY MR. SNELL: By Dr. Klinge.</p> <p>10 MR. CARTMELL: Objection. And move to</p> <p>11 strike this statement of counsel.</p> <p>12 A. And I agree with you completely, and</p> <p>13 that should tell you something about Klinge's</p> <p>14 expertise, as far as a stress urinary incontinence</p> <p>15 surgeon, which he is not. He's a mesh expert.</p> <p>16 But he's not a transvaginal surgeon. He's never</p> <p>17 been involved in one of these cases. So you</p> <p>18 search around and find one reference where he's</p> <p>19 quoting something in the book, okay, that's what</p> <p>20 it is.</p> <p>21 Q BY MR. SNELL: He doesn't just quote</p> <p>22 something in a book. He's actually citing data,</p> <p>23 randomized trial data on TVT versus an alternative</p> <p>24 mesh; doesn't he?</p> <p>25 A. I'm saying he is not a surgeon. He's</p>	<p>1 know?</p> <p>2 MR. SNELL: So the question is would</p> <p>3 you -- well, I take it he's read Dr. Klinge's</p> <p>4 writings. He's seen Dr. Klinge's statements.</p> <p>5 MR. CARTMELL: What writings are you</p> <p>6 asking him about? If you have writings about</p> <p>7 DynaMesh that you want to ask him about, put them</p> <p>8 in front of him. Why all the questions about</p> <p>9 studies and things that you don't even let him</p> <p>10 look at.</p> <p>11 MR. SNELL: He can look at anything he</p> <p>12 wants.</p> <p>13 MR. CARTMELL: Then put it in front of</p> <p>14 him.</p> <p>15 MR. SNELL: It's not my job to put it</p> <p>16 in front of him. It's the job of your witness to</p> <p>17 bring his file. Secondly, he cites to Klinge</p> <p>18 about 100 times in the report, and not once does</p> <p>19 he acknowledge any of this.</p> <p>20 MR. CARTMELL: If you're going to ask</p> <p>21 him about a study specifically on it that's on his</p> <p>22 reliance list, then bring it with you and ask him</p> <p>23 questions and let him look at it so it can be</p> <p>24 fair. How about that? How about that?</p> <p>25 MR. SNELL: He could bring his own</p>
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<p>1 not providing expertise as a pelvic surgeon like I</p> <p>2 am. He's a mesh expert, a very good one, but he</p> <p>3 is not a pelvic surgeon.</p> <p>4 Q. Do you know how many royalties</p> <p>5 Dr. Klinge gets with regard to his work with the</p> <p>6 German DynaMesh mesh?</p> <p>7 A. I have not heard a number, no.</p> <p>8 Q. You know he does get money from that</p> <p>9 mesh; right?</p> <p>10 A. I just said I don't know. I don't</p> <p>11 know. I'm not a faithful apostle of Dr. Klinge.</p> <p>12 I don't know what he does.</p> <p>13 Q. Do you acknowledge he's got a</p> <p>14 conflict --</p> <p>15 MR. CARTMELL: All you got to do is</p> <p>16 answer do you know or not.</p> <p>17 A. I do not know.</p> <p>18 Q BY MR. SNELL: You know that he has a</p> <p>19 conflict of interest when it comes to DynaMesh;</p> <p>20 don't you?</p> <p>21 MR. CARTMELL: What it comes to what?</p> <p>22 MR. SNELL: DynaMesh, D-y-n-a-M-e-s-h.</p> <p>23 It's a mesh that's not even available here in the</p> <p>24 United States.</p> <p>25 MR. CARTMELL: So then why would he</p>	<p>1 file. How about that? That was asked and</p> <p>2 requested of him, Tom.</p> <p>3 MR. CARTMELL: You have everything he</p> <p>4 has reviewed.</p> <p>5 MR. SNELL: Tom, my experts bring</p> <p>6 their file to the depositions.</p> <p>7 MR. CARTMELL: Wrong.</p> <p>8 MR. SNELL: You remember when you</p> <p>9 deposed Denise Selzer she showed up with nine</p> <p>10 boxes of stuff.</p> <p>11 MR. CARTMELL: Denise Selzer did.</p> <p>12 MR. SNELL: Christina Pramudji showed</p> <p>13 up with boxes and boxes and boxes of stuff.</p> <p>14 MR. CARTMELL: Not when I deposed her.</p> <p>15 MR. SNELL: Get for real. You know</p> <p>16 she did. Crazy.</p> <p>17 A. But to address your question, as far</p> <p>18 as conflict of interest, if he truly does have</p> <p>19 conflict of interest and bias, then based upon</p> <p>20 this here he's coming out in support of TVT. So I</p> <p>21 see a fault in your logic.</p> <p>22 Q BY MR. SNELL: I don't have a logic.</p> <p>23 I'm asking you a question.</p> <p>24 A. Well, I know you don't have a logic</p> <p>25 and that's what I've been pointing out.</p>

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<p>1 Q. My question is: You were aware of</p> <p>2 these writings by Klinge with regard to TVT and</p> <p>3 that mesh and the specific intended use of stress</p> <p>4 urinary incontinence before you wrote your report;</p> <p>5 right?</p> <p>6 A. I'm aware of this reference.</p> <p>7 Q. Yes. You were --</p> <p>8 A. The one that I'm holding, Exhibit 20.</p> <p>9 I don't recall if I've ever been aware of this.</p> <p>10 Q. The plaintiffs' lawyers never gave</p> <p>11 that to you?</p> <p>12 A. I don't recall if they have. I have</p> <p>13 thousands of pages they've sent me. It may have</p> <p>14 been in there somewhere. I have not seen this.</p> <p>15 Again, if he were a pelvic surgeon, I would be</p> <p>16 putting weight into his comments on gold standard</p> <p>17 and things. But all he's doing is parroting what</p> <p>18 he's read somewhere else. So, again, it is what</p> <p>19 it is.</p> <p>20 Q. Can you point me to any other</p> <p>21 publications by Klinge where he assesses the TVT</p> <p>22 retropubic device in the application of stress</p> <p>23 incontinence and discusses the clinical studies on</p> <p>24 that device like he did in that paper I just</p> <p>25 showed you, Exhibit 20?</p>	<p>1 So, again, I'm agreeing with you and disagreeing</p> <p>2 with you at the same time. Not to be difficult.</p> <p>3 MR. SNELL: Okay. Let's take a quick</p> <p>4 break so I can get organized.</p> <p>5 (Recessed from 3:05 p.m. to</p> <p>6 3:07 p.m.)</p> <p>7 Q BY MR. SNELL: I want to ask you about</p> <p>8 your opinions about the mechanical cut of the TVT</p> <p>9 retropubic device.</p> <p>10 You've mechanically cut mesh before?</p> <p>11 A. Just the sacrocolpopexy mesh. Not</p> <p>12 sling mesh.</p> <p>13 Q. And did it ever concern you when you</p> <p>14 were cutting sacrocolpopexy mesh mechanically?</p> <p>15 A. It didn't. And now it does.</p> <p>16 Q. Do you still cut sacrocolpopexy mesh?</p> <p>17 A. No. We modified -- well, we're in the</p> <p>18 process of modifying it to using Restoril, which</p> <p>19 will not hopefully have that problem. It's</p> <p>20 already hemmed. And that is a concern of mine</p> <p>21 which I now counsel my patients on.</p> <p>22 Q. And is it fair to say that you believe</p> <p>23 the laser cut TVT mesh is defective?</p> <p>24 A. I think it's treated one -- to</p> <p>25 specifically answer your question, yes.</p>
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<p>1 MR. CARTMELL: Object to the form. It</p> <p>2 misstates the actual paper.</p> <p>3 A. He has studied extensively hernia</p> <p>4 meshes. TVT is a hernia mesh. But to put all the</p> <p>5 dots together as you very narrowed it down to, the</p> <p>6 answer to that is no, not that I am aware of.</p> <p>7 Q BY MR. SNELL: My focus is the</p> <p>8 intended application of the treatment of stress</p> <p>9 incontinence and those studies alone.</p> <p>10 You haven't seen that paper or those</p> <p>11 papers?</p> <p>12 A. As you word it there, I have not seen</p> <p>13 that. The intended application of the TVT mesh</p> <p>14 was actually for hernias. Not for female stress</p> <p>15 incontinence. So, again, he has studied the</p> <p>16 intended purpose of that mesh. He has not studied</p> <p>17 it when it's been put into the vagina.</p> <p>18 Q. For the TVT device, that's what I'm</p> <p>19 referring to for its intended -- you've</p> <p>20 acknowledged that the TVT retropubic device is</p> <p>21 intended to treat stress urinary incontinence;</p> <p>22 right?</p> <p>23 A. The device is, but the mesh intended</p> <p>24 use was for hernias, which was then extended to</p> <p>25 the application of stress urinary incontinence.</p>	<p>1 Q. I didn't see in your expert report</p> <p>2 where you cite to any TVT studies with regard to</p> <p>3 clinical complications occurring at a</p> <p>4 statistically higher rate with mechanical cut TVT</p> <p>5 mesh as compared to laser cut TVT mesh.</p> <p>6 Is that a fair summary of your report?</p> <p>7 A. You are correct. I have not heard of</p> <p>8 a study with that. However, I'm basing that on</p> <p>9 Nilsson's comment of a four-time -- four times</p> <p>10 increased risk of vaginal extrusion with a laser</p> <p>11 cut.</p> <p>12 Q. What comment is this by Nilsson? I'm</p> <p>13 sorry.</p> <p>14 A. That was in one of the documents I</p> <p>15 read. I don't know where I read it, but it's in</p> <p>16 the document.</p> <p>17 Q. What methodology did you use to select</p> <p>18 that one quote by Nilsson?</p> <p>19 A. Because he is arguably one of the</p> <p>20 world's experts on it. And so I value his opinion</p> <p>21 on this.</p> <p>22 Q. Do you also value his statement in the</p> <p>23 company documents that he will not use laser cut</p> <p>24 mesh; that he only uses mechanical cut mesh?</p> <p>25 A. Absolutely. That's supporting what I</p>

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<p>1 just said.</p> <p>2 Q. So you're aware that Nilsson only --</p> <p>3 in the company documents, reports that he will</p> <p>4 only use mechanical cut mesh?</p> <p>5 A. That's -- I don't know what his recent</p> <p>6 statements are, but that the document that I read,</p> <p>7 which that source can be found, he said he would</p> <p>8 not use the laser cut because of the four times</p> <p>9 increased risk of vaginal extrusion, and he would</p> <p>10 only use the mechanical. Then I read the other</p> <p>11 individuals stating the exact opposite. So I get</p> <p>12 conflicting evidence. I have not seen, to the</p> <p>13 best of my knowledge and it may be out there</p> <p>14 somewhere, a study, comparative, randomized</p> <p>15 clinical study of the two. I've not seen it.</p> <p>16 Q. Are you aware of any TVT retropubic</p> <p>17 clinical data that reports that there's a higher</p> <p>18 rate of complications with mechanically cut mesh</p> <p>19 compared to laser cut mesh?</p> <p>20 A. I don't think overall there's going to</p> <p>21 be a higher risk from one or the other. They're</p> <p>22 both bad and both have their set of complications.</p> <p>23 So you're trading one set of problems for another</p> <p>24 set of problems.</p> <p>25 Q. What studies are you specifically</p>	<p>1 ever read on TVT. If you have something</p> <p>2 different, then I'll keep an open mind. I have</p> <p>3 yet to see any paper describe we're using</p> <p>4 mechanically cut or we're using laser cut. So I</p> <p>5 can't base it upon that.</p> <p>6 Q. Okay. So when I was asking about what</p> <p>7 papers you were talking about, I thought you were</p> <p>8 talking about Ethicon company documents and not</p> <p>9 medical literature.</p> <p>10 A. No. That was one of them. The</p> <p>11 internal documentation -- I'll just be clear.</p> <p>12 As I stated in the previous answer,</p> <p>13 internal Ethicon documentations, medical</p> <p>14 literature, the emails back and forth, and then my</p> <p>15 clinical experience. That's how I came by it.</p> <p>16 I am not here today to say that laser</p> <p>17 cut is better or worse. They're both bad in my</p> <p>18 opinion.</p> <p>19 Q. So with regard to your selection of</p> <p>20 which company documents to put in your expert</p> <p>21 report on this mechanical cut issue, what was your</p> <p>22 methodology in selecting those particular company</p> <p>23 documents?</p> <p>24 A. My methodology of what I reviewed is</p> <p>25 very simple. Every document that I was provided</p>
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<p>1 relying upon for your opinion with regard to the</p> <p>2 mechanical cut TVT retropubic mesh, if any?</p> <p>3 A. Well, that's what I'm talking about.</p> <p>4 The methodology that I have used with this,</p> <p>5 concerning specifically mechanically cut, is</p> <p>6 obviously the internal documentation, with</p> <p>7 complaints coming in about the fraying, roping,</p> <p>8 particle loss, the inflammation. Reviewing of the</p> <p>9 papers talking about various different</p> <p>10 complications. My clinical experience dealing</p> <p>11 with patients. Last week alone, there's one</p> <p>12 patient. Week before that, three, which were all</p> <p>13 TVT patients. Where that I see this mechanically</p> <p>14 cut mesh. Then my discussion with colleagues at</p> <p>15 international and national meetings. So all that</p> <p>16 is going into it.</p> <p>17 Q. You said the papers. You reference</p> <p>18 papers. Are you talking about Ethicon documents?</p> <p>19 A. Correct. Well, I mean the medical</p> <p>20 literature, too.</p> <p>21 Q. That's what I'm asking. What medical</p> <p>22 literature on TVT reports complications</p> <p>23 attributed -- attributed to the mechanical cut</p> <p>24 nature of the mesh?</p> <p>25 A. The defect in -- and every paper I've</p>	<p>1 with internal documentation from Ethicon I</p> <p>2 reviewed.</p> <p>3 Q. So you were provided those by the</p> <p>4 plaintiffs' lawyers?</p> <p>5 A. Correct.</p> <p>6 Q. My question to you is this: Let's</p> <p>7 focus on your methodology for which ones you</p> <p>8 decided to cite in your expert report as support</p> <p>9 for your points.</p> <p>10 What was the methodology in that?</p> <p>11 A. You have to -- you have to analyze --</p> <p>12 MR. CARTMELL: Well, just for</p> <p>13 clarification, you mean because they're all cited</p> <p>14 in his report.</p> <p>15 MR. SNELL: No, they're not.</p> <p>16 MR. CARTMELL: There's a reliance</p> <p>17 list.</p> <p>18 MR. SNELL: There's a reliance list,</p> <p>19 but he cited certain things.</p> <p>20 MR. CARTMELL: Okay. So you're</p> <p>21 distinguishing between what's in a footnote versus</p> <p>22 what's in the reliance list that's attached.</p> <p>23 MR. SNELL: Of course, because, I'm</p> <p>24 sure, everything in the reliance list doesn't</p> <p>25 support the things he says.</p>

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<p>1 MR. CARTMELL: Well, everything on his</p> <p>2 reliance list is information he used in forming</p> <p>3 his opinions and relies on.</p> <p>4 MR. SNELL: You're speaking -- you're</p> <p>5 doing a speaking objection.</p> <p>6 MR. CARTMELL: Well, I'm responding to</p> <p>7 your statement you just made. You're talking</p> <p>8 about only the citations in the report.</p> <p>9 MR. SNELL: Yes. That is my question.</p> <p>10 That is my question. Do I need to repose it again</p> <p>11 so we have a clear record?</p> <p>12 THE DEPONENT: No.</p> <p>13 Q BY MR. SNELL: Why don't we just do it</p> <p>14 again.</p> <p>15 A. That's fine.</p> <p>16 Q. Otherwise there's just going to be</p> <p>17 four pages of gap.</p> <p>18 What specific methodology, did you use</p> <p>19 in determining what Ethicon documents you would</p> <p>20 cite to in support of your opinions where you</p> <p>21 listed them in the footnotes?</p> <p>22 A. Okay. I have to look at the body of</p> <p>23 knowledge out there on medical literature, my</p> <p>24 clinical experience and what I see day to day,</p> <p>25 correlating that with what was known and discussed</p>	<p>1 be your methodology for excluding it or not</p> <p>2 referencing it in your report?</p> <p>3 MR. CARTMELL: It was on his reliance</p> <p>4 list.</p> <p>5 A. Yeah. To a certain extent, surgeon</p> <p>6 preference is important, and then also not</p> <p>7 important. So certain surgeons choose to do one</p> <p>8 product over the another. The fact that</p> <p>9 51 percent like the mechanical cut and 49 don't,</p> <p>10 it doesn't matter to me. Again, we're not talking</p> <p>11 about one product being great and the other one</p> <p>12 being horrible. They're both bad. So to me it's</p> <p>13 immaterial.</p> <p>14 Q BY MR. SNELL: Did you assess or look</p> <p>15 at the reported rates of sales of mechanical cut</p> <p>16 versus laser cut in the United States?</p> <p>17 A. Well, from my angle as a doctor, the</p> <p>18 needs of the patient come first. And sales are</p> <p>19 not an issue that I'm going to be concerned about.</p> <p>20 Q. So the answer is, no, you didn't look</p> <p>21 at that?</p> <p>22 A. The answer is what I just stated.</p> <p>23 Q. Sir, my question is very simple, which</p> <p>24 is: Did you look at it?</p> <p>25 I understand you want to give me a</p>
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<p>1 in the Ethicon documents, whether it be from their</p> <p>2 scientists, from their medical experts, from their</p> <p>3 clinicians calling in, correlating that and does</p> <p>4 it all fit. Everything has to fit logically,</p> <p>5 okay, and that was what was included in this.</p> <p>6 Q. So, for example, did you see company</p> <p>7 documents that indicated that the majority of</p> <p>8 surgeons in the United States actually prefer</p> <p>9 mechanical cut mesh as opposed to laser cut?</p> <p>10 A. I've seen that, yes. Well, I'm sorry.</p> <p>11 Let me take that -- strike that.</p> <p>12 I do remember seeing and reading that</p> <p>13 certain physicians would not change to the laser</p> <p>14 cut. I can't say that the majority did. I also</p> <p>15 see that certain surgeons would not use the</p> <p>16 mechanical one because of the fraying and the</p> <p>17 particle loss. So I don't know the percentage of</p> <p>18 who uses what.</p> <p>19 Q. So you were not provided documents</p> <p>20 that state that the majority of surgeons in the</p> <p>21 United States who use TVT prefer the mechanical</p> <p>22 cut mesh as opposed to laser cut; fair?</p> <p>23 A. I may have been provided that. I</p> <p>24 don't recall that specific document.</p> <p>25 Q. If that document existed, what would</p>	<p>1 speech on things, but if you could just give me a</p> <p>2 yes or no answer, then I can move on. If you say</p> <p>3 no, then I'm going to move on.</p> <p>4 A. Well, no, because my speech, as you</p> <p>5 did, is based upon my taking care of patients who</p> <p>6 are crying in my office from pain. So I don't</p> <p>7 dismiss it as a speech. But medical marketing</p> <p>8 sales are not something that's going to factor</p> <p>9 into my decision.</p> <p>10 Q. I believe earlier you were talking</p> <p>11 about complications, and I think it may have been</p> <p>12 around mesh exposures, where you said there would</p> <p>13 be numerous different factors like patient</p> <p>14 factors, surgeon factors, the mesh.</p> <p>15 Do you recall that?</p> <p>16 A. Yeah. Concerning vaginal exposure. I</p> <p>17 don't recall if I mentioned patient factors</p> <p>18 involved in it, but, I mean, maybe I did. I</p> <p>19 don't -- I'd have to see exactly what I said.</p> <p>20 Q. I wrote it down.</p> <p>21 A. It's a multifactorial problem that</p> <p>22 leads to that complication.</p> <p>23 Q. What are the patient factors involved?</p> <p>24 A. Well, that's difficult because it's --</p> <p>25 I don't know of anyone ever studying to show</p>

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<p>1 consistently a patient factor being involved in</p> <p>2 the exposures. Smoking, I'm not aware of.</p> <p>3 Obesity, I'm unaware of. Vaginal atrophy -- I</p> <p>4 don't know of patient factors that can be</p> <p>5 consistently proven to be a factor in vaginal</p> <p>6 exposure.</p> <p>7 Q. You are -- vaginal atrophy is a</p> <p>8 condition that women have that can progress or get</p> <p>9 worse as they get older in their postmenopausal</p> <p>10 years if not supplemented with some type of</p> <p>11 estrogen; fair?</p> <p>12 A. There's the possibility of that, yes.</p> <p>13 Not in all cases.</p> <p>14 Q. But is that a common finding in women</p> <p>15 who are postmenopausal that there is some degree</p> <p>16 of vaginal atrophy?</p> <p>17 A. It's not uncommon, let's put it that</p> <p>18 way. So, yeah, it does occur.</p> <p>19 Q. Is there a recognized weight</p> <p>20 classification specific to stress urinary</p> <p>21 incontinence slings that has been endorsed and put</p> <p>22 out by any of the pertinent professional medical</p> <p>23 societies?</p> <p>24 A. Pertaining to what? I guess I don't</p> <p>25 understand your question. That they should or</p>	<p>1 standard thing that's out there. Same thing goes</p> <p>2 for pore size, too.</p> <p>3 Q. And my focus is on the intended use</p> <p>4 with the stress incontinence device and the</p> <p>5 application to treat stress incontinence.</p> <p>6 A. Closest thing I think would have to be</p> <p>7 a Clave study, breaking it down to the various</p> <p>8 weights, I think, if I'm answering your question</p> <p>9 correctly. But that's not as it pertains</p> <p>10 specifically to SUI.</p> <p>11 Q. Right. That's what I'm looking for is</p> <p>12 SUI.</p> <p>13 A. I am not aware of that specific narrow</p> <p>14 application.</p> <p>15 Q. For SUI, the slings are typically</p> <p>16 around 1 centimeter wide.</p> <p>17 A. 1 to 1.5, probably.</p> <p>18 Q. Ethicon's TVT is reported to be about</p> <p>19 1.1 centimeters; correct?</p> <p>20 A. As it comes out of the box, which is</p> <p>21 an important distinction.</p> <p>22 Q. Yeah.</p> <p>23 A. But, yeah, they're all about that</p> <p>24 width.</p> <p>25 Q. Is it a fair statement that all of the</p>
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<p>1 should not get a TVT?</p> <p>2 Q. No, no. For the intended use of</p> <p>3 stress urinary incontinence.</p> <p>4 Is there a recognized weight</p> <p>5 classification system for slings?</p> <p>6 A. Well, no. The BMI is the standard</p> <p>7 what is used. And but there's not, as it pertains</p> <p>8 specifically to SUI treatments.</p> <p>9 Q. I think you and I -- we weren't on the</p> <p>10 same wavelength.</p> <p>11 For the weight of the mesh --</p> <p>12 A. Oh, okay.</p> <p>13 Q. -- and the intended use of treating</p> <p>14 stress urinary incontinence, is there a recognized</p> <p>15 weight classification system that's endorsed by</p> <p>16 the professional societies?</p> <p>17 A. No. As far as -- even in industry,</p> <p>18 industry and surgical societies, there is -- as</p> <p>19 far as I know, there is no specific</p> <p>20 classification. I think they have heavy weight --</p> <p>21 you know, Cobb and others taught about heavy</p> <p>22 weight. So there would be that. And above</p> <p>23 certain -- or below certain numbers would become</p> <p>24 medium weight and lightweight. I don't know if I</p> <p>25 can -- I can't quote a society that has this</p>	<p>1 mesh slings, synthetic mesh slings that are used</p> <p>2 to treat stress urinary incontinence have a weight</p> <p>3 of more than 60 grams per meter squared?</p> <p>4 MR. CARTMELL: Object to the form.</p> <p>5 May call for speculation.</p> <p>6 Answer if you know.</p> <p>7 A. Yeah. All I can speak to is Aris,</p> <p>8 which I know is at 70. TVT at 105. I don't know</p> <p>9 that the other products.</p> <p>10 Q. BY MR. SNELL: You read Moalli's paper</p> <p>11 on the biomechanical evaluation of slings?</p> <p>12 A. I read it at one point in time. Not</p> <p>13 recently.</p> <p>14 Q. It has a table in there where it has</p> <p>15 the reported weights of the different slings.</p> <p>16 A. Okay.</p> <p>17 Q. Is that a paper you're relying on, the</p> <p>18 Moalli paper?</p> <p>19 A. That's in my reliance list. But I'm</p> <p>20 just saying I haven't read it recently. You're</p> <p>21 referring to the 2007 paper?</p> <p>22 Q. Give me the title and I'll tell you.</p> <p>23 A. Tensile Properties of Five Commonly</p> <p>24 Used Mid-Urethral Slings Relative to the TVT, by</p> <p>25 Moalli, et al., June of 2007. Published in 2008.</p>

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<p style="text-align: right;">Page 238</p> <p>1 Excuse me.</p> <p>2 Q. That's it. Yeah. Is that a paper</p> <p>3 you're relying on?</p> <p>4 A. Yes.</p> <p>5 Q. Are there any studies in the stress</p> <p>6 incontinence application with the use of TVT that</p> <p>7 show that a lighter weight mesh is either more</p> <p>8 efficacious -- strike that.</p> <p>9 Let me just say is more efficacious</p> <p>10 than the TVT?</p> <p>11 A. Can you rephrase the question, because</p> <p>12 as I'm reading it. I can't quite understand.</p> <p>13 Q. Absolutely. Yeah.</p> <p>14 Are there any clinical studies</p> <p>15 evaluating efficacy in women with stress urinary</p> <p>16 incontinence that show that a lighter weight mesh</p> <p>17 works better than the TVT retropubic device?</p> <p>18 MR. CARTMELL: Object to the form.</p> <p>19 A. No, I don't think the weight of the</p> <p>20 mesh --</p> <p>21 MR. CARTMELL: Can I -- can I get</p> <p>22 this? Can we take a break.</p> <p>23 MR. SNELL: Yeah. An opportune time.</p> <p>24 (Recessed from 3:31 p.m. to</p> <p>25 3:32 p.m.)</p>	<p style="text-align: right;">Page 240</p> <p>1 of treating stress urinary incontinence?</p> <p>2 A. No. I've only seen it in pelvic organ</p> <p>3 prolapse data and in meshes. Meshes for hernia</p> <p>4 repairs, but it was not extrapolated, even though</p> <p>5 Ethicon knew about it, into stress urinary</p> <p>6 incontinence.</p> <p>7 Q. All right. And you're not testifying</p> <p>8 that a lighter weight mesh would have worked</p> <p>9 better than the TVT mesh in the TVT retropubic</p> <p>10 application to treat stress urinary incontinence;</p> <p>11 are you?</p> <p>12 MR. CARTMELL: Are you talking about</p> <p>13 efficacy only?</p> <p>14 MR. SNELL: I can go with efficacy</p> <p>15 first.</p> <p>16 A. There is no data out there on it.</p> <p>17 That would be an important thing to do before a</p> <p>18 launch is to study that to determine efficacy</p> <p>19 prior to widespread use.</p> <p>20 Q BY MR. SNELL: You would agree it's a</p> <p>21 benefit for the TVT retropubic device that they do</p> <p>22 have studies of 5 years, 10 years, or more</p> <p>23 duration in the literature?</p> <p>24 MR. CARTMELL: Object to the form.</p> <p>25 A. Yes, as we mentioned concerning</p>
<p style="text-align: right;">Page 239</p> <p>1 MR. SNELL: Can you read back the</p> <p>2 question?</p> <p>3 (The reporter read the record as</p> <p>4 requested.)</p> <p>5 A. As is worded there, I'm not aware of</p> <p>6 it. I mean, Cobb and internal Ethicon documents</p> <p>7 talk about lighter weight being better, fewer</p> <p>8 complications, sort of things. But as you</p> <p>9 specifically narrow it down to TVT, there is not</p> <p>10 that study.</p> <p>11 Q BY MR. SNELL: And my question -- the</p> <p>12 initial question was on efficacy.</p> <p>13 A. No. As far as I know.</p> <p>14 Q. Okay.</p> <p>15 A. There is nothing out there, as far as</p> <p>16 the lightweights.</p> <p>17 The move was in hernias and pelvic</p> <p>18 organ prolapse to go to lighter weight because of</p> <p>19 the complications, but that was decided against</p> <p>20 with TVT.</p> <p>21 Q. And so my question is I want to get</p> <p>22 into -- ask you about the complications.</p> <p>23 Are you aware of any clinical studies</p> <p>24 showing a lower rate of complications in women who</p> <p>25 receive a lighter weight mesh for the intended use</p>	<p style="text-align: right;">Page 241</p> <p>1 efficacy, but not safety.</p> <p>2 Q BY MR. SNELL: Well, there's --</p> <p>3 A. The lighter meshes, the larger pore,</p> <p>4 lighter weight meshes are for complications. Not</p> <p>5 for efficacy.</p> <p>6 Q. And I understand you say that with</p> <p>7 regard to prolapse and hernia. My question to you</p> <p>8 is: With regard to complications, is it your</p> <p>9 opinion that a lighter weight mesh was used in the</p> <p>10 application of TVT for the treatment of stress</p> <p>11 incontinence, cut to 1.1 centimeters, that there</p> <p>12 would be a lower complication rate?</p> <p>13 A. There's the theoretical possibility of</p> <p>14 that. However, my ultimate opinion is no meshes</p> <p>15 should be placed transvaginally.</p> <p>16 Q. Fair enough.</p> <p>17 You mentioned the Clave study. That</p> <p>18 was not a study that reported on the use of the</p> <p>19 TVT retropubic device in women who had been</p> <p>20 treated for stress urinary incontinence; correct?</p> <p>21 A. Correct. That was, as I recall, for</p> <p>22 pelvic organ prolapse.</p> <p>23 Q. Is this the Clave 2010 paper?</p> <p>24 A. Correct.</p> <p>25 Q. Okay.</p>

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<p>1 (Exhibit 21 marked.)</p> <p>2 Q BY MR. SNELL: I've given you</p> <p>3 Exhibit 21. This is the paper we were referencing</p> <p>4 by Clave; correct?</p> <p>5 A. Correct.</p> <p>6 Q. Okay. This is the paper where they</p> <p>7 start out with 100 explants and they only</p> <p>8 subjected 84 of them to scanning electron</p> <p>9 microscopy; correct?</p> <p>10 A. Well, there were 100 explants, and I'd</p> <p>11 have to look through how many got evaluated with</p> <p>12 SEM. I don't recall the exact number. If you say</p> <p>13 it's 82, I'm okay with that.</p> <p>14 Q. 84.</p> <p>15 A. 84.</p> <p>16 Q. I wouldn't misrepresent to you. Right</p> <p>17 there.</p> <p>18 A. Okay. I got it.</p> <p>19 Q. You go it?</p> <p>20 A. Um-hum. Thank you.</p> <p>21 Q. Under SEM analysis, it found that less</p> <p>22 than half of the implants had this surface</p> <p>23 cracking; correct?</p> <p>24 A. It's an extremely high number, yes.</p> <p>25 Q. There were 35 out of 84?</p>	<p>1 I read that correctly; didn't I?</p> <p>2 A. I didn't see where you're reading.</p> <p>3 Q BY MR. SNELL: Right here.</p> <p>4 A. 266 or 267?</p> <p>5 Q. 266 at the bottom right.</p> <p>6 A. Oh, yes. I see it now. Yes. I'm</p> <p>7 sorry.</p> <p>8 Q. So when they try to do the other</p> <p>9 testings, the FTIR, the DSCs, they did not confirm</p> <p>10 degradation; correct?</p> <p>11 MR. CARTMELL: Object to the form.</p> <p>12 Misstates the statement.</p> <p>13 A. Again, I'd have to see where you're</p> <p>14 reading. I don't know where this is coming from.</p> <p>15 Q BY MR. SNELL: This is a question to</p> <p>16 you based on this study.</p> <p>17 A. Again, I'd have to -- it's been a</p> <p>18 while since I've gone over this paper. So I'd</p> <p>19 have to find all the nuances you're discussing. I</p> <p>20 mean, they describe degradation. They describe</p> <p>21 cracking, and to me that's degradation.</p> <p>22 But the exact etiology of it, I don't</p> <p>23 recall from the study what they came up with.</p> <p>24 Q. Well, when you see this cracking, that</p> <p>25 could be polypropylene or something other than</p>
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<p>1 A. Yeah. That's -- that's a worrisome</p> <p>2 number to me. I mean, it's 35 out of 80 women are</p> <p>3 having this degradation going on.</p> <p>4 Q. And besides just looking at the</p> <p>5 pictures on the SEM and seeing the cracking and</p> <p>6 saying that must be degradation, when they</p> <p>7 actually did tests to analyze and see if it was</p> <p>8 degradation, those testings did not show it was</p> <p>9 degradation; correct?</p> <p>10 A. You'd have to show me where you're</p> <p>11 referring to.</p> <p>12 Q. How about --</p> <p>13 A. Because to me, degradation is</p> <p>14 cracking, brittle --</p> <p>15 Q. 266.</p> <p>16 A. 266?</p> <p>17 Q. 266. You know that after doing the</p> <p>18 scanning electron microscopy, they subjected them</p> <p>19 to FTIR, DSC analyses; correct?</p> <p>20 A. Correct.</p> <p>21 Q. And if you look at the bottom of</p> <p>22 page 266, they reported that several hypotheses</p> <p>23 concerning the degradation of the PP are described</p> <p>24 below. None of these, particularly indirect</p> <p>25 oxidation, could be confirmed in this study.</p>	<p>1 polypropylene; correct?</p> <p>2 MR. CARTMELL: Object to the form.</p> <p>3 A. Well, all I can quote, as far as my</p> <p>4 experience, obviously I have these papers which I</p> <p>5 reviewed, but I can only correlate that</p> <p>6 macroscopically to my surgical experience. When I</p> <p>7 take out these meshes, which I did, it happened to</p> <p>8 be a TVT-Secur last week. Where you hold it, it's</p> <p>9 brittle, it cracks, it breaks, it's sharp; it</p> <p>10 pokes the finger. Okay. To me that is</p> <p>11 degradation.</p> <p>12 Now, on the microscopic level, you</p> <p>13 know, I don't know what exactly they call and what</p> <p>14 specific words they use to describe that process.</p> <p>15 Q BY MR. SNELL: They didn't say it was</p> <p>16 brittle and broke and cracked in your fingers in</p> <p>17 Clave; correct?</p> <p>18 A. No, they didn't say that. I'm saying</p> <p>19 that's what me and my daily experience, including</p> <p>20 just last week -- that's what I feel, and that's</p> <p>21 what I'm calling degradation of the product.</p> <p>22 Q. Clave and them show pictures of</p> <p>23 scanning electron microscopy with surface</p> <p>24 cracking?</p> <p>25 A. Yes. But none of these are TVT, you</p>

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<p>1 said. So this is a very important study. Seems 2 like they're raising red flags. 3 Next step is Ethicon needs to study it 4 with their specific product. 5 Q. And in Clave the explants have been 6 explanted because of reported complications; 7 correct? 8 A. I believe so, yes. 9 Q. There was no control group in this 10 study of explants for which there was no 11 complication reported; correct? 12 A. Well, yeah, the complication was a 13 manifestation of underlying pathology. So, no, 14 you don't have a control because you're not going 15 to go operate on women who do not have a 16 complication yet. 17 Q. And so the authors were unable to 18 state whether or not this amount and this type of 19 surface cracking is something that occurs in 20 non-explanted meshes? 21 A. I mean, you're really narrowing down 22 the focus of this. Again, it's not a TVT product, 23 but they were not able to say -- I guess, I'm not 24 really following your question. I'm sorry. 25 Q. What I was getting at is on page 269,</p>	<p>1 vaginal mesh and tape fibers explants in women, 2 okay. And that included TVT. They were removed 3 four to seven years after, and it demonstrated 4 degradation on SEM, and surface cracks, which 5 corresponds to my clinical experience. 6 Q. In these seven explants, was there any 7 oxidation found of the TVT mesh? 8 A. Oxidation is the process by which you 9 get degradation. So in order to study for 10 oxidation, you have to do some pretty 11 sophisticated chemical studies on the microscopic 12 level as far as what macrophages are doing. I 13 don't know -- I'm not an expert on how exactly 14 that would be accomplished. But if there's 15 degradation, I know there's been an inflammatory 16 response, which inflammatory response causes 17 oxidation, is one of the main reasons with 18 peroxides, hypochloric acid, et cetera. 19 Q. Has the reported degradation in these 20 seven explants been confirmed in any standardized 21 test, such as chemical analyses? 22 A. I'm unaware. I have to go back to the 23 study and see what they've done from that. From 24 my angle as a surgeon, I would want the company 25 then to go back and look at some of this stuff for</p>
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<p>1 they say, "For obvious ethical reasons this study 2 did not provide the opportunity to analyze vaginal 3 implants from non-pathological situations. 4 Therefore, prediction of normal in vivo material 5 aging and the range of consequences in the 6 clinical state beyond the observed samples is not 7 possible." 8 A. That is correct. 9 Q. Okay. Can you point to any clinical 10 studies, any studies on the TVT device to treat 11 women that showed degradation of that TVT mesh? 12 And if you're looking at your report, 13 just tell me what page so I can -- 14 A. Page 13. 15 Q. Give me a second. Okay. 16 A. Specifically if you limit it to just 17 TVT, obviously I quote multiple different studies 18 looking at polypropylene and the foreign body 19 response, the inflammatory response, the 20 degradation, you have Mary, et al., Costello, 21 Clave, Wood. But on page 15 at the very top, the 22 first full sentence says, "In 2015 seven 23 implants." And that is -- if you look down at 24 reference 11, it's a Russian name, I think. 25 T-z-a-r-t-z-e-v-a. In-depth nano-investigation of</p>	<p>1 me. 2 Q. Are there any studies that you're 3 aware of on the TVT device that correlate and show 4 that a particular complication was caused by 5 degradation? 6 A. Well, no. Degradation is part of the 7 cascade of events. You have an implantation of a 8 product that causes a foreign body response and 9 inflammatory response, which then the immune 10 system comes in with the various different dumping 11 of various different product to try and to 12 eliminate the foreign body, infection, and then 13 degradation occurs. 14 So you're not going to find something 15 where it's just degradation. It's a cascade of 16 events. 17 Q. Is there any clinical literature that 18 shows any complications are caused by degradation? 19 A. Well, I would say every study that 20 there's a vaginal erosion or extrusion is evidence 21 of degradation. Yeah, every time that I do an 22 exam on a patient and find this brittle, cracking, 23 hard mesh that is evidence of degradation. 24 Q. Are there any studies that report 25 degradation played any kind of role in a vaginal</p>

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<p style="text-align: right;">Page 250</p> <p>1 erosion or extrusion following a TVT?</p> <p>2 A. Well, yeah, this T-z-a-r-t-z-e-v-a on</p> <p>3 page 15. There are seven explants, including TVT,</p> <p>4 that were removed after implantation. Okay. So</p> <p>5 some sort of complication. And they found</p> <p>6 degradation there.</p> <p>7 (Exhibit 22 marked.)</p> <p>8 MR. CARTMELL: Just so you know,</p> <p>9 Doctor, for the record, a lot of times people call</p> <p>10 it the Zimmern study. It's easier to the</p> <p>11 pronounce.</p> <p>12 THE DEPONENT: Yeah. Phillippe at UT</p> <p>13 Southwestern.</p> <p>14 Q BY MR. SNELL: This is the paper you</p> <p>15 were referencing?</p> <p>16 A. Correct. It's an abstract.</p> <p>17 Q. It's T-z-a-r-t-z-e-v-a.</p> <p>18 A. Yeah. It's Zimmern. Phillippe</p> <p>19 Zimmern at Utah Southwestern's paper.</p> <p>20 Q. And this wasn't seven TVT devices as</p> <p>21 you put in your report; was it?</p> <p>22 A. No. I said including the TVT. So not</p> <p>23 all were TVT.</p> <p>24 Q. Right. In fact, how many of these</p> <p>25 were TVTs?</p>	<p style="text-align: right;">Page 252</p> <p>1 different devices; correct?</p> <p>2 A. That's right. That's five different</p> <p>3 devices. So TVT could be three of them. What I'm</p> <p>4 saying is this particular abstract does not break</p> <p>5 it down into which one is which.</p> <p>6 Q. And you don't have a clue then as to</p> <p>7 whether one was a TVT or two or three; correct?</p> <p>8 A. As I've stated, the abstract does not</p> <p>9 state that.</p> <p>10 Q. And this abstract doesn't state what</p> <p>11 complications, if any, occurred with the TVT;</p> <p>12 correct?</p> <p>13 A. No. It states they were explanted for</p> <p>14 some reason.</p> <p>15 Q. And you note in this study they looked</p> <p>16 for peaks of oxidation, and they didn't find any;</p> <p>17 right?</p> <p>18 A. Okay. You know, they did or didn't.</p> <p>19 Immaterial to me because it shows degradation.</p> <p>20 Degradation can occur because of multiple</p> <p>21 different reasons, but they didn't find it on this</p> <p>22 particular study.</p> <p>23 Q. And they didn't try to say the</p> <p>24 clinical effect, if any, of a 7-nanometer degree</p> <p>25 of surface cracking; correct?</p>
<p style="text-align: right;">Page 251</p> <p>1 A. I don't know if it actually says.</p> <p>2 Seven explants. But I don't think they break it</p> <p>3 down into what -- which one has what.</p> <p>4 Q. Well, they had a Gynemesh; correct?</p> <p>5 A. Correct.</p> <p>6 Q. And that's not a TVT retropubic</p> <p>7 device; correct?</p> <p>8 A. No. It's an Ethicon product.</p> <p>9 Q. Then they had a TVT; correct?</p> <p>10 A. Yes.</p> <p>11 Q. They identify one TVT in this study</p> <p>12 you cite; right?</p> <p>13 MR. CARTMELL: Object to the form.</p> <p>14 Misstates the paper.</p> <p>15 A. Again, I'd have to see where it is.</p> <p>16 Q BY MR. SNELL: Well, you cite to it,</p> <p>17 Doctor. So I'm telling you, they cite to one TVT</p> <p>18 in this study; right?</p> <p>19 MR. CARTMELL: That's not what it</p> <p>20 says. It misstates the paper.</p> <p>21 A. That's not what it -- it says seven</p> <p>22 explants were studied covering a range of</p> <p>23 currently MT devices, Gynemesh, TVT, TOT, Sparc,</p> <p>24 and mini sling.</p> <p>25 Q BY MR. SNELL: So that's five</p>	<p style="text-align: right;">Page 253</p> <p>1 A. Well, no, you have to extrapolate.</p> <p>2 There was a complication on all seven of these.</p> <p>3 They had degradation. They had cracking.</p> <p>4 Something went wrong. Was it infection? Was it</p> <p>5 pain? Extrusion? Contraction? Dyspareunia. I</p> <p>6 don't know. I'm just going -- they don't state in</p> <p>7 this paper, in this abstract.</p> <p>8 Q. Do you believe that there are any</p> <p>9 clinically significant complications that occur</p> <p>10 because of degradation?</p> <p>11 A. Yes.</p> <p>12 Q. And where do you identify them in your</p> <p>13 report? I'm sorry.</p> <p>14 A. That is in the section on Degradation,</p> <p>15 beginning on page 13 through top of 16.</p> <p>16 Q. So what specific complications, if</p> <p>17 any, arise because of degradation?</p> <p>18 A. Well, that's what we've talked about</p> <p>19 multiple times here. Degradation is one of the</p> <p>20 steps of the problems. It starts with</p> <p>21 implantation of a foreign body in a contaminated</p> <p>22 environment that creates inflammation, foreign</p> <p>23 body response. Macrophages come in. They dump</p> <p>24 their hydrogen peroxide, hypochloric acid. The</p> <p>25 product breaks down. It creates more of an</p>

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<p>1 inflammatory process. And it's a vicious cycle, 2 which leads to then scarring, contraction, scar 3 plate, dyspareunia, pelvic pain, urethral erosion, 4 bladder erosion. 5 So degradation is one of the steps of 6 this cascade. 7 Q. Are you aware of any reliable 8 scientific studies that show the degree to which 9 degradation causes any of these complications you 10 just identified as compared to surgical technique, 11 patient factors or any other causal elements? 12 A. See, that's exactly what I've been 13 trying to state this entire time. The whole 14 device, as marketed, is bad because surgeons play 15 a role. The patient may or may not. I think 16 that's questionable. We talked about that 17 already. I can't find an identifiable source 18 there. But then you have a bad product put in. 19 So the whole thing is bad. It's 20 multifactorial reasons why certain number of these 21 patients have devastating complications. 22 Q. If a patient has a mesh exposure, do 23 you assume that degradation was a cause? 24 A. Depends partly on when it occurred. 25 However, I believe Clave said it was independent</p>	<p>1 on. 2 Q. So that's what I'm asking you then, 3 okay? 4 How do you know which exposures 5 degradation played a role in, when in Clave they 6 didn't even see degradation, except in 45 percent 7 of them? 8 A. Okay. Then -- I mean -- 9 Q. That's a scientific question I'm 10 getting at. 11 A. Well, yes and no with that. So 12 45 percent of the patients, based on Clave, had 13 degradation and complications. That means the 14 other 55 had other factors, surgical, implantation 15 technique, roping, curling, whatever, to cause 16 complications. For myself, as a surgeon who takes 17 care of these patients, I ultimately don't care 18 what causes the problem. I've got a problem I've 19 got to deal with. 20 So if we want to base it upon Clave, 21 45 percent of these complications could have 22 occurred due to degradation. It's 45 percent of 23 patients who have been damaged due to degradation 24 of the product. 25 Q. Is that an opinion you hold</p>
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<p>1 of time of implantation that they found their 2 degradation. The longer it's in, intuitively and 3 based upon the data and based upon like 4 Klosterhalfen says 15 years, degradation 5 contraction continue, that the longer it's in, 6 there's going to be more problems with it. 7 Q. Well, Clave, they didn't even find 8 surface cracking in half of the explants. 9 A. But they found it in half. So tell a 10 patient, great, half of you aren't going to have 11 it at that point in time, but the other half are. 12 Q. Maybe we're not communicating. 13 We've already gone through Clave, and 14 it didn't show degradation or surface cracking in 15 more than half of the implants. 16 A. It was like 55 percent or something 17 like that, or in that ballpark. 18 Q. Right. Right. 19 So in those 55 percent, right, some of 20 those patients would have had exposures; right? 21 A. Possibly. I don't believe the article 22 states it. 23 Q. Yet they didn't see surface cracking; 24 right? 25 A. So that means something else was going</p>	<p>1 45 percent -- 2 A. No. 3 Q. -- of exposures occur because of 4 degradation? 5 A. No, I don't. We're saying based upon 6 the Clave study. I have yet to see -- and this 7 would be a very good study to be done, and it 8 should be done by Ethicon, if there's a concern 9 and they want to take care of patients and prevent 10 women from being damaged of studying these things. 11 Q. But I'm here to learn your opinion; 12 right. 13 What percent of the women who have an 14 exposure is that caused by degradation? 15 A. I guess -- 16 Q. If you can't say or you don't know, 17 tell me that. But if you have a number, then I 18 want to know the methodology by which you come 19 to -- come to that number. 20 A. If I have a patient who is seeing me 21 two or three days after a mesh sling with 22 exposure, that's not due to degradation, okay. 23 Q. That's her wound hasn't healed up? 24 A. That's right. 25 Q. Maybe it was placed superficially;</p>

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<p>1 correct?</p> <p>2 A. Within a couple of days, that is not</p> <p>3 the mesh causing -- now, it will impair healing,</p> <p>4 because there's a foreign body reaction to things.</p> <p>5 But it's not due to degradation.</p> <p>6 Q. Well --</p> <p>7 A. If somebody is occurring longer than</p> <p>8 that, let's say beyond the initial healing period.</p> <p>9 Six weeks is traditionally where the body will be</p> <p>10 at roughly 98 percent of its strength. That's our</p> <p>11 usual, going by that six weeks. Beyond that, if</p> <p>12 exposure or an event like that occurs, degradation</p> <p>13 in my opinion is going to be one of the main</p> <p>14 underlying factors for it, in combination with the</p> <p>15 infection, inflammatory response.</p> <p>16 Q. And what's the methodology for that</p> <p>17 statement?</p> <p>18 A. Exact -- based upon the literature and</p> <p>19 my clinical experience on a daily basis, including</p> <p>20 in the past two weeks, four -- three TVT and one</p> <p>21 TVT-Secur patient I dealt with.</p> <p>22 Q. Let's talk about the literature</p> <p>23 because I can't go and look at your charts, okay.</p> <p>24 In the literature, what studies show</p> <p>25 that if an exposure occurs beyond six weeks did</p>	<p>1 patients who have mesh who have devastating</p> <p>2 complications, that's a statement you'd made</p> <p>3 earlier; correct?</p> <p>4 A. Multiple times that's based on my</p> <p>5 clinical experience in talking and discussing it</p> <p>6 with surgical colleagues.</p> <p>7 Q. So you're not relying on any</p> <p>8 literature to report the rates of devastating</p> <p>9 complications with TVT retropubic; correct?</p> <p>10 MR. CARTMELL: Not relying on what?</p> <p>11 Object to the form of that.</p> <p>12 A. No. I think certain patients --</p> <p>13 certain patients.</p> <p>14 Certain studies like Hou, et al.,</p> <p>15 which was also Phillippe Zimmern, who I personally</p> <p>16 talked to about his paper, where they had slings,</p> <p>17 where after -- they had only removed for pain.</p> <p>18 19 percent had persistent pain. Just to beat you</p> <p>19 to the punch, they did not break it down into TVT</p> <p>20 or not.</p> <p>21 Q BY MR. SNELL: And they also didn't</p> <p>22 report a denominator from which all those patients</p> <p>23 were drawn from; correct?</p> <p>24 A. They did not. That denominator, as</p> <p>25 far as I know, is not known.</p>
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<p>1 degradation play a major role, I think you said?</p> <p>2 A. Then we go back -- let's go back to</p> <p>3 Clave then. And we've said -- we've admitted</p> <p>4 roughly 45 percent of those patients had</p> <p>5 degradation. Okay. So based purely and just on</p> <p>6 that paper, that will be my opinion, that</p> <p>7 45 percent for that paper.</p> <p>8 But what I'm saying is it has been</p> <p>9 inadequately studied elsewhere. Something that</p> <p>10 needs to be done.</p> <p>11 Q. Did Clave rule out other causal</p> <p>12 factors for the exposures in his study?</p> <p>13 A. I have --</p> <p>14 Q. If he did, tell me how he did it.</p> <p>15 A. No. I would have to look at the paper</p> <p>16 and see all that he's looked at.</p> <p>17 Q. This study you talk about that you</p> <p>18 think Ethicon should have done, how would you</p> <p>19 design that study?</p> <p>20 A. The basic unfortunate reality is it --</p> <p>21 I don't know if it could be done. Hence the</p> <p>22 reason why I am anti-mesh in the vagina, because</p> <p>23 you cannot safely make this thing work and cannot</p> <p>24 do it in a long-term.</p> <p>25 Q. When you say that there are some</p>	<p>1 Q. And that's an issue with case series,</p> <p>2 where you do not have a denominator, thus one</p> <p>3 cannot compute reliably the incidence; correct?</p> <p>4 A. The true incidence, unfortunately, is</p> <p>5 not known, and it needs to be known because some</p> <p>6 of these people's lives are destroyed.</p> <p>7 Q. So in a case series like you</p> <p>8 mentioned, a major limitation to that series is</p> <p>9 that it does not speak to the incidence of those</p> <p>10 complications; correct?</p> <p>11 A. I would disagree with you that it's a</p> <p>12 major limitation. It is a limit you cannot</p> <p>13 extrapolate across the board, but in his series,</p> <p>14 in a very good reconstructive surgeon's hands,</p> <p>15 19 percent of SUIs had persistent chronic pain.</p> <p>16 Q. And you don't know how many were TVT;</p> <p>17 correct?</p> <p>18 A. That is correct.</p> <p>19 Q. More likely than not, they were not</p> <p>20 going to have persistent pain; correct?</p> <p>21 MR. CARTMELL: Object to the form. I</p> <p>22 think it's vague and ambiguous. May call for</p> <p>23 speculation.</p> <p>24 A. Oh, I see what you're saying. Okay.</p> <p>25 In the follow-up of these individuals,</p>

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<p>1 there were 19 percent that had permanent pain.</p> <p>2 Statically speaking, that means that you get rid</p> <p>3 of the mesh, 81 percent got better. Therefore,</p> <p>4 the mesh is the source for the pain.</p> <p>5 MR. SNELL: Move to strike.</p> <p>6 Q BY MR. SNELL: It was more likely that</p> <p>7 the patients would get better as opposed to having</p> <p>8 persistent pain in the study you just told me</p> <p>9 about; correct?</p> <p>10 A. During the duration of their</p> <p>11 follow-up, 81 percent of the patients, once the</p> <p>12 mesh was relieved, had resolution of their pain.</p> <p>13 Q. You wrote in your report that you</p> <p>14 believe that the TVT mesh is cytotoxic?</p> <p>15 A. Correct.</p> <p>16 Q. You saw that cytotoxicity -- that data</p> <p>17 were presented to the FDA in the 510K for TVT;</p> <p>18 right? I can withdraw it and clean it up.</p> <p>19 Dr. Elliott, you saw that, in the 510K</p> <p>20 for TVT retropubic device to treat stress</p> <p>21 incontinence, Ethicon reported the cytotoxicity</p> <p>22 data that you reference in your report to the FDA;</p> <p>23 right?</p> <p>24 A. I don't -- it's been a long time since</p> <p>25 I read the 510K submission. I have to look to see</p>	<p>1 the FDA and the people what reviewed the TVT</p> <p>2 retropubic device 510K with regard to their</p> <p>3 determination as to whether the TVT retropubic</p> <p>4 device is safe and effective?</p> <p>5 A. No. I mean, I've seen that the --</p> <p>6 that the FDA has made those statements. But what</p> <p>7 I'm saying is, I don't know if they've received</p> <p>8 all of the documentation and then their opinions</p> <p>9 on that, as far as the cytotoxicity, et cetera.</p> <p>10 Q. Okay.</p> <p>11 (Exhibit 23 marked.)</p> <p>12 Q BY MR. SNELL: I marked as Exhibit 23</p> <p>13 the FDA's statement, Considerations about Surgical</p> <p>14 Mesh for SUI, 2013.</p> <p>15 This is a document you're familiar</p> <p>16 with?</p> <p>17 A. Correct.</p> <p>18 Q. And you see this is off the FDA web</p> <p>19 site as well?</p> <p>20 A. That is correct.</p> <p>21 Q. Page last updated March 27, 2013;</p> <p>22 correct? I'll show you?</p> <p>23 A. Yes, I see it.</p> <p>24 Q. And it says on the first page, "the</p> <p>25 safety and effectiveness of multi-incision slings</p>
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<p>1 if they talk about the severely cytotoxic, marked</p> <p>2 cytotoxic part of these studies.</p> <p>3 Q. You know in 2013 the FDA released a</p> <p>4 statement regarding synthetic slings for the</p> <p>5 treatment of stress incontinence?</p> <p>6 A. They had a release.</p> <p>7 Q. And you saw the FDA wrote in that</p> <p>8 release that the full length mid-urethral sling</p> <p>9 like TVT retropubic device has been shown to be</p> <p>10 safe and effective up to one year; correct?</p> <p>11 A. I would have to see that study. And</p> <p>12 let's just -- or not the study. But that</p> <p>13 publication. But let's just say they say that</p> <p>14 exactly as you did.</p> <p>15 At one year.</p> <p>16 Q. Right.</p> <p>17 A. Again, that's the limitation of all</p> <p>18 those statements.</p> <p>19 Q. And has the FDA, to your knowledge,</p> <p>20 ever concluded that the TVT retropubic device --</p> <p>21 that the mesh is cytotoxic?</p> <p>22 A. I have not seen that in any of their</p> <p>23 writings. I don't know also what information</p> <p>24 they've received.</p> <p>25 Q. You have not seen any documents from</p>	<p>1 is well established in clinical trials that</p> <p>2 followed patients for up to one year. Longer</p> <p>3 follow-up data is available in the literature, but</p> <p>4 there are fewer of these long-term studies</p> <p>5 compared to studies with one-year follow-up."</p> <p>6 Correct?</p> <p>7 A. Correct. That's what they state.</p> <p>8 Q. Let me ask you this question.</p> <p>9 It would be a true statement that the</p> <p>10 safety and effectiveness of the Burch</p> <p>11 colposuspension, the autologous slings, biologic</p> <p>12 slings, cadaveric slings, all the different stress</p> <p>13 incontinence options -- that the safety and</p> <p>14 effectiveness of them has been assessed more, to a</p> <p>15 greater volume in studies reporting on 12 months</p> <p>16 or less as compared to longer term studies;</p> <p>17 correct?</p> <p>18 MR. CARTMELL: Object to the form.</p> <p>19 A. That would be true, that most SUI</p> <p>20 studies are short-term because they're easier to</p> <p>21 do, and that's why the data is poor to moderately</p> <p>22 poor.</p> <p>23 Q BY MR. SNELL: So what you just said</p> <p>24 there, let me make sure I understand you.</p> <p>25 Shorter term studies assessing stress</p>

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<p>1 urinary incontinence surgery are easier to do than</p> <p>2 longer term studies?</p> <p>3 A. Correct.</p> <p>4 Q. That applies across the board?</p> <p>5 A. Correct. I mean, shorter term studies</p> <p>6 are easier to do because they're short-term. You</p> <p>7 have less patient loss to follow-up those things.</p> <p>8 Q. What studies, if any, in women show</p> <p>9 that cytotoxicity causes any complications with</p> <p>10 the use of TVT retropubic device?</p> <p>11 A. There have been none because the issue</p> <p>12 of cytotoxicity has not been released to the</p> <p>13 general public. Therefore, someone is not going</p> <p>14 to study that if they don't even know it exists.</p> <p>15 Q. Do you know the 510K documents on TVT</p> <p>16 are publicly available at the FDA and available</p> <p>17 through a Google search on the web sites?</p> <p>18 A. They may be. I don't -- I don't know</p> <p>19 because I don't search that.</p> <p>20 Q. You've never attempted that search?</p> <p>21 A. Not with this device. I've done it</p> <p>22 with the ObTape, and I couldn't find it.</p> <p>23 Q. Okay. Are there any complications</p> <p>24 that you believe are due to cytotoxicity?</p> <p>25 A. Possible --</p>	<p>1 60 months follow-up.</p> <p>2 Of that 2.4 percent, can you say how</p> <p>3 many of those 17 patients had the defective</p> <p>4 vaginal healing because of cytotoxicity, or is</p> <p>5 that known?</p> <p>6 A. That has not been studied to date,</p> <p>7 because as I mentioned, I didn't even know the</p> <p>8 cytotoxicity report even existed until I got</p> <p>9 involved in this. So no one out in the community,</p> <p>10 our physicians, researchers are going to know that</p> <p>11 exists. They're not going to study it.</p> <p>12 Q. What percent of TVT retropubic devices</p> <p>13 is the mesh cytotoxic?</p> <p>14 A. Well, from what they state here, if</p> <p>15 this TVT is studied and has been shown to have</p> <p>16 marked cytotoxicity or severely cytotoxic in these</p> <p>17 two references and that mesh is put in the</p> <p>18 patient, then 100 percent of those have the</p> <p>19 potential for cytotoxicity.</p> <p>20 Q. All right. So if 100 percent have a</p> <p>21 cytotoxic mesh, why is it that 97.6 percent in the</p> <p>22 Wang study who were followed out beyond 60 months</p> <p>23 didn't have any defective vaginal healing?</p> <p>24 A. It's going to be, again,</p> <p>25 multifactorial. The vaginal healing, the duration</p>
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<p>1 Q. Let me make sure because I want to</p> <p>2 focus on TVT, not leave a vague question out there</p> <p>3 because we were last talking about ObTape.</p> <p>4 So for the TVT retropubic device, are</p> <p>5 there complications which you believe are caused</p> <p>6 by cytotoxicity?</p> <p>7 A. In theory, possibly all of them,</p> <p>8 because cytotoxicity is cell death. Cell death</p> <p>9 will increase the foreign body response, the</p> <p>10 inflammatory response, subsequently increase the</p> <p>11 degradation, cracking, increase pain, increase the</p> <p>12 potential for infection. I'm saying possibly. It</p> <p>13 could be.</p> <p>14 Q. Okay.</p> <p>15 A. That has not been studied to date.</p> <p>16 Q. Okay. For example, you pointed me to</p> <p>17 the Wang paper earlier, and we looked at it, and</p> <p>18 there was a 2.4 percent rate of exposure; right?</p> <p>19 A. There was 17 out of 700 that had</p> <p>20 impaired vaginal healing. And I can't recall the</p> <p>21 data beyond that.</p> <p>22 Q. It was 2.4 percent?</p> <p>23 A. Okay. I remember the 2.4 percent.</p> <p>24 Q. Okay. So working with that number,</p> <p>25 2.4 percent, and we looked and there was more than</p>	<p>1 of follow-up, is smoking going to play a role,</p> <p>2 obesity, impaired vaginal status. And, again,</p> <p>3 what's going to be these people 15, 20, 30 years</p> <p>4 from now.</p> <p>5 MR. SNELL: Move to strike as</p> <p>6 nonresponsive.</p> <p>7 Q. BY MR. SNELL: My question was: If</p> <p>8 100 percent of people have the cytotoxic TVT</p> <p>9 retropubic mesh, why is it that 97.6 percent of</p> <p>10 the patients in Wang did not have the defective</p> <p>11 vaginal healing?</p> <p>12 A. See the -- not to be critical, but</p> <p>13 your logic is impaired. 100 percent of people who</p> <p>14 smoke don't get lung cancer. 100 percent of</p> <p>15 people exposed to asbestos don't get mesothelioma.</p> <p>16 100 percent exposed to TVT aren't going to have</p> <p>17 those devastating complications, but certain ones</p> <p>18 do.</p> <p>19 Q. And that's what I'm trying to</p> <p>20 understand and test here. All right.</p> <p>21 What is it about the 97.6 percent of</p> <p>22 the patients who didn't have defective vaginal</p> <p>23 healing that led this cytotoxic mesh to have no</p> <p>24 role or no effect on the --</p> <p>25 A. Okay. We decreased it down. You said</p>

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<p>1 defective vaginal healing.</p> <p>2 Q. I was trying to use the words you</p> <p>3 said.</p> <p>4 A. You're correct; 2.4 percent had</p> <p>5 defective vaginal healing. That is just one of</p> <p>6 the complications. Not all cytotoxicity or</p> <p>7 degradation is going to go just to mesh extrusion.</p> <p>8 I'm talking pain, contraction, roping, the</p> <p>9 degradation process. Pelvic pain, vaginal pain,</p> <p>10 dyspareunia.</p> <p>11 So they are just saying, just in this</p> <p>12 limiting it, 2.4 percent had defective vaginal</p> <p>13 healing. Okay. So that's narrowing the number I</p> <p>14 talked about before, okay. I cannot answer the</p> <p>15 question as to why don't all. All I know is that</p> <p>16 to me this is a red flag and patients and doctors</p> <p>17 need to be warned of that possible cytotoxicity.</p> <p>18 Q. For example, we looked at the number</p> <p>19 of patients who reported dyspareunia and there was</p> <p>20 four out of that group.</p> <p>21 A. Five complained of pain. Four</p> <p>22 complained of dyspareunia, and then five</p> <p>23 complained of vaginal bleeding.</p> <p>24 Q. Right. So for the dyspareunia,</p> <p>25 right -- we addressed this somewhat. I will</p>	<p>1 be studied.</p> <p>2 Q BY MR. SNELL: Okay. That was my</p> <p>3 question.</p> <p>4 Of -- and I was really focused on</p> <p>5 dyspareunia. Of the four patients with</p> <p>6 dyspareunia, you can't say, reliably,</p> <p>7 scientifically, which if any of those four were</p> <p>8 caused by cytotoxicity; correct?</p> <p>9 A. No. You are correct because all I can</p> <p>10 say is there was some defect in the product that</p> <p>11 caused this. I cannot attribute that just to</p> <p>12 cytotoxicity.</p> <p>13 Q. And Wang did not rule out other</p> <p>14 factors besides the mesh; did he?</p> <p>15 A. I don't recall Wang giving a specific</p> <p>16 opinion on that, what necessitated.</p> <p>17 Q. How would you design a study like you</p> <p>18 state Ethicon should do with regard to</p> <p>19 cytotoxicity to see what effect, if any, it would</p> <p>20 have on complications for women receiving the TVT</p> <p>21 retropubic device for stress incontinence?</p> <p>22 A. You cannot ethically construct a study</p> <p>23 of putting a product in that has the possibility</p> <p>24 of cytotoxicity in a patient for a quality of life</p> <p>25 study. You can't do it. It would never get</p>
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<p>1 represent to you I calculated that, and it's</p> <p>2 0.56 percent. Okay. 4 out of 700.</p> <p>3 For that 0.56 percent of patients who</p> <p>4 had dyspareunia, is there a way to scientifically</p> <p>5 reliably say, which, if any of them, that was</p> <p>6 caused by cytotoxicity? And if there is, I want</p> <p>7 to know the methodology by which you would</p> <p>8 conclude that.</p> <p>9 A. That would require a study by Ethicon</p> <p>10 to do that. And so all I know is we have a red</p> <p>11 flag. We have marked cytotoxicity. We have</p> <p>12 complication. These are just limiting to the</p> <p>13 specific one. I cannot point to a paper and say</p> <p>14 that because then it has not been studied because</p> <p>15 individuals didn't know to study it. It needs to</p> <p>16 be studied, though.</p> <p>17 Q. So I think in fairness, the answer to</p> <p>18 my question was, no, you don't know that; correct?</p> <p>19 MR. CARTMELL: Objection. Asked and</p> <p>20 answered. He just answered your question.</p> <p>21 A. No. And I will reiterate just what I</p> <p>22 said again. Cytotoxicity is a red flag of</p> <p>23 something going on. We know there's cytotoxicity</p> <p>24 there. How much of a role it plays in all the</p> <p>25 other complications, I don't know. That needs to</p>	<p>1 approved and no woman would accept it.</p> <p>2 Q. Am I correct that for the pore size of</p> <p>3 the TVT mesh you cannot reliably say</p> <p>4 scientifically what complications are caused due</p> <p>5 to pore size in TVT patients?</p> <p>6 MR. CARTMELL: Object to the form.</p> <p>7 A. As I've stated multiple times, as</p> <p>8 outlined in my report, we have an overall system</p> <p>9 design failure.</p> <p>10 Specifically small pore, what role is</p> <p>11 that playing in percentage of the complications.</p> <p>12 No, I cannot say that.</p> <p>13 Q BY MR. SNELL: You have not studied</p> <p>14 the rates of complications of stress urinary</p> <p>15 incontinence slings to see whether there is a</p> <p>16 statistically significant different rate of</p> <p>17 complications that occurs dependent upon pore</p> <p>18 size; correct?</p> <p>19 A. You are partly correct. However, we</p> <p>20 do know from the hernia mesh data and the Vypro</p> <p>21 mesh data that complications can be reduced with a</p> <p>22 large poor lightweight. It has not been extended</p> <p>23 down into the TVT like it should have been. So</p> <p>24 you are correct. That data does not exist and it</p> <p>25 should exist.</p>

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<p>1 Q. Actually, that data do exist to some</p> <p>2 degree in the application of stress urinary</p> <p>3 incontinence because there are data like the</p> <p>4 Cochrane Reviews that show that multifilament</p> <p>5 meshes have higher complication rates than</p> <p>6 monofilament meshes; correct?</p> <p>7 A. Yes. But we're talking about the TVT</p> <p>8 here. And I'm talking about lightweight hernia</p> <p>9 mesh. You know, Ethicon employees all agree,</p> <p>10 lightweight, small -- or large pore reduce</p> <p>11 complications. The Cochrane has nothing to do</p> <p>12 with lightweight, large pore meshes. It doesn't</p> <p>13 exist, as far as I know, for slings.</p> <p>14 Q. The multifilament meshes assessed in</p> <p>15 the Cochrane Review that had higher rates of</p> <p>16 complications compared to the monofilament meshes</p> <p>17 like TVT have a smaller pore size than the TVT</p> <p>18 mesh; correct?</p> <p>19 A. No. You are correct, but we're</p> <p>20 talking -- yes, I agree with you.</p> <p>21 The ObTape, the ProteGen, the</p> <p>22 Gortexes, the Amid 3's have higher implications</p> <p>23 than TVT. I agree with you. But what I'm saying</p> <p>24 is the next level up above TVT, the lightweight,</p> <p>25 large pore meshes, it does not exist. The</p>	<p>1 body.</p> <p>2 Q. No surgeon in the world that you're</p> <p>3 aware of has ever taken a larger pore, lighter</p> <p>4 weight hernia mesh, cut it down to 1.1</p> <p>5 centimeters, put it in a sheath and placed it</p> <p>6 retropubically, like the TVT retropubic device;</p> <p>7 correct?</p> <p>8 A. I am unaware of anybody doing that.</p> <p>9 Including Ethicon.</p> <p>10 Q. Therefore, you are unaware of any</p> <p>11 studies in the application of a stress urinary</p> <p>12 incontinence tape that show that when put in that</p> <p>13 configuration and used as the TVT is,</p> <p>14 retropubically, with the passage of trochars, that</p> <p>15 there is a lower complication rate in stress</p> <p>16 incontinent women; correct?</p> <p>17 MR. CARTMELL: Object to the form. I</p> <p>18 believe it misstates his opinions in this case and</p> <p>19 the report.</p> <p>20 Q. BY MR. SNELL: Go ahead.</p> <p>21 A. And therein lies a huge deficit of</p> <p>22 what Ethicon should have done. They knew the data</p> <p>23 on hernia meshes and prolapse meshes. Large pore,</p> <p>24 lightweight fewer complications. They did not</p> <p>25 take the next step of extrapolating that to TVT,</p>
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<p>1 technology exists for it, but the product has not</p> <p>2 been done in any studies for women in stress</p> <p>3 incontinence.</p> <p>4 Q. Right. Okay. So those larger pore,</p> <p>5 lighter weight meshes have not been cut down to</p> <p>6 1.1 centimeters, put into sheaths and tested by</p> <p>7 anyone; correct?</p> <p>8 A. That is correct. In my opinion it</p> <p>9 should have been.</p> <p>10 Q. All right. What physicians and</p> <p>11 surgeons -- well, strike that.</p> <p>12 If physicians and surgeons wanted to</p> <p>13 test larger pore, lighter weight hernia meshes in</p> <p>14 the application of stress incontinence, couldn't</p> <p>15 they cut slings made of ULTRAPRO and test it for</p> <p>16 incontinence?</p> <p>17 A. I can't speak to what surgeons could</p> <p>18 or could not do.</p> <p>19 Q. Well, you cut mesh and put it in the</p> <p>20 body however you wanted; didn't you?</p> <p>21 A. No.</p> <p>22 Q. You didn't do that for sacrocolpopexy?</p> <p>23 A. I configured an already Y-shaped mesh.</p> <p>24 I did not take something and create something new.</p> <p>25 I just configured it to fit into the patient's</p>	<p>1 because, as they said, now their TVT data no</p> <p>2 longer holds up. So they made a decision not to</p> <p>3 do that.</p> <p>4 Q. BY MR. SNELL: Well, you would</p> <p>5 criticize Ethicon for wanting to have a product</p> <p>6 that has longer term data than all the other</p> <p>7 meshes out there, including ones you, yourself,</p> <p>8 have used?</p> <p>9 MR. CARTMELL: Objection.</p> <p>10 Argumentative.</p> <p>11 A. Well, I have no problem with them</p> <p>12 having long-term studies out there, but I'm saying</p> <p>13 they're not focused on safety. And I'm saying if</p> <p>14 they knew, if a corporation knew that there were a</p> <p>15 better product available and they chose not to,</p> <p>16 purely for marketing, that is unethical,</p> <p>17 unacceptable.</p> <p>18 Q. BY MR. SNELL: How do they know it's</p> <p>19 better in the application of stress urinary</p> <p>20 incontinence when the sling is only 1.1</p> <p>21 centimeters?</p> <p>22 A. They should --</p> <p>23 MR. CARTMELL: Object to the form. I</p> <p>24 don't understand the question.</p> <p>25 A. No.</p>

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<p>1 MR. SNELL: I mean, you're -- I mean, 2 what you're talking about is Ethicon's state of 3 mind, and that will not fly with this judge. So 4 I'm going to withdraw that question. 5 MR. CARTMELL: Let's take a break. 6 MR. SNELL: That's fine. 7 (Recessed from 4:25 p.m. to 8 4:42 p.m.) 9 MR. SNELL: You do know that I'm here 10 to question him on his New Jersey report as well? 11 MR. CARTMELL: No, I didn't know that. 12 MR. SNELL: Ben didn't tell you that? 13 MR. CARTMELL: Hum-um. 14 MR. SNELL: He said he wanted it all 15 done in one sitting. So -- 16 MR. CARTMELL: He told me next week in 17 Minneapolis. 18 MR. SNELL: That's only case specific 19 on Watkins. I'm doing the New Jersey general 20 stuff today. 21 MR. CARTMELL: Okay. 22 MR. SNELL: That's what they told me. 23 MR. CARTMELL: I'm not doing that. If 24 you're telling me you're going longer than 25 7 hours --</p>	<p>1 there at 6:00, I'm going to get my brains beat in. 2 I'm not doing that. 3 MR. SNELL: Well, then we're going to 4 have to agree that whenever I can make it and the 5 doctor make it, we'll do the New Jersey general 6 TVT portion. 7 MR. CARTMELL: Well, that's fine. But 8 I'm not -- 9 MR. SNELL: Because the person who's 10 deposing him in Watkins -- 11 MR. CARTMELL: Look, there's -- 12 MR. SNELL: Let me just say something. 13 MR. CARTMELL: This is ridiculous that 14 you take 7-hour depositions. 15 MR. SNELL: The person disposing him 16 in Watkins is only case specific. That was all 17 agreed to and hammered out -- 18 MR. CARTMELL: Nobody told me that. 19 MR. SNELL: -- between Ben and 20 everybody in these big mass emails. All right. 21 Well, let's just -- let's jump on it, okay. 22 MR. CARTMELL: Okay. 23 MR. SNELL: We'll find something that 24 works. But I'm telling you -- and you know it. I 25 know you're tied up and I'm tied up, through the</p>
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<p>1 MR. SNELL: Yeah. 2 MR. CARTMELL: -- I ain't doing that. 3 MR. SNELL: Well, why didn't Ben tell 4 you that, because that's the agreement. 5 MR. CARTMELL: Nobody told me that. 6 MR. SNELL: That's the agreement I put 7 in the emails, too. Ben was having -- 8 MR. CARTMELL: This was the 9 consolidation deposition. 10 MR. SNELL: Right. And then but Ben 11 said, but you need to do his New Jersey generally 12 TVT at the same sitting because Watkins case 13 specific is next week. And I said, okay, I'll 14 start that after I finish the design defect. It's 15 all in the emails. I'm surprised he did not tell 16 you that. 17 MR. CARTMELL: He didn't tell me and 18 I'm not doing it. 19 MR. SNELL: Is that on the record. I 20 mean, because I came here and flew here to do 21 both. And I'm not available next weekend, okay, 22 because I have my own experts. 23 MR. CARTMELL: I'm not available 24 tonight, and I -- I agreed to do this, and I have 25 something I have to be at at 6:00, and if I'm not</p>	<p>1 5th, okay. But I'm here today, prepared to do the 2 New Jersey general after this one. 3 MR. CARTMELL: Well, I'm not. 4 MR. SNELL: I know. I know. 5 MR. CARTMELL: I'm not doing that. 6 I'm not doing 9 hours -- 7 MR. SNELL: I don't know why they 8 didn't tell you. 9 MR. CARTMELL: I'm not making the 10 doctor do 9 hours of deposition. That's 11 ridiculous. This is crazy. We're, again, going 12 over stuff that I think you even covered in his 13 first depo. 14 MR. SNELL: I've only deposed him on 15 Prolift. 16 MR. CARTMELL: But that doesn't 17 matter. A lot of this stuff has been talked 18 about. 19 MR. SNELL: No. But this is in the 20 application of the design of TVT for stress 21 incontinence. That was the agreement. 22 MR. CARTMELL: Go. You've got 23 48 minutes. 24 MR. SNELL: That was the agreement, 25 okay. That's why I came here. And I'm prepared</p>

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<p>1 to do that.</p> <p>2 MR. CARTMELL: I wish I had known.</p> <p>3 MR. SNELL: I wish they would have</p> <p>4 told you, to be honest with you. And I wish they</p> <p>5 would have told me, because I was preparing to go</p> <p>6 out tomorrow. And as for the length of deposition</p> <p>7 being ridiculous, in New Jersey some of my experts</p> <p>8 were deposed for more than 13 hours.</p> <p>9 MR. CARTMELL: I just can't believe</p> <p>10 this. But go ahead.</p> <p>11 MR. SNELL: All right. So we'll pick</p> <p>12 it up. Are you ready, Doc.</p> <p>13 THE DEPONENT: Yes, I am.</p> <p>14 Q BY MR. SNELL: You got your report</p> <p>15 there handy?</p> <p>16 A. Yes, I do.</p> <p>17 Q. Can you just turn to page 20.</p> <p>18 A. Yes.</p> <p>19 Q. The picture there, that is not a</p> <p>20 picture of the TVT retropubic device to treat</p> <p>21 stress urinary incontinence; is that correct?</p> <p>22 A. That is correct.</p> <p>23 Q. All right. The width of whatever that</p> <p>24 mesh is is a lot more than 1 centimeter; correct?</p> <p>25 A. I don't know the dimensions on that.</p>	<p>1 section of my report, which I have down here</p> <p>2 starting on roughly page 17, it appears.</p> <p>3 In there I say, Ethicon's medical</p> <p>4 director stated that TVT can shrink -- generally</p> <p>5 believe TVT mesh would shrink approximately</p> <p>6 30 percent post implantation, and that is an</p> <p>7 internal document.</p> <p>8 MR. SNELL: So respectfully move to</p> <p>9 strike.</p> <p>10 Q. BY MR. SNELL: My question was: Are</p> <p>11 you aware of any clinical studies that assess the</p> <p>12 TVT in the application of stress urinary</p> <p>13 incontinence and reported that there was no</p> <p>14 shrinkage with the TVT mesh?</p> <p>15 A. That there was no shrinkage? I'm</p> <p>16 unaware of any studies that's documented no</p> <p>17 shrinkage.</p> <p>18 Q. Okay. The Vypro mesh, you're aware</p> <p>19 that -- let me back up.</p> <p>20 So you make reference to Vypro and</p> <p>21 ULTRAPRO in your report; I believe; correct?</p> <p>22 A. Vypro. I'd have to look and see with</p> <p>23 ULTRAPRO, where I put that. But Vypro, yes.</p> <p>24 Q. In the context of a hernia or animal</p> <p>25 study; correct?</p>
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<p>1 I have to go back to the original document.</p> <p>2 Q. Well, if you look at the number of</p> <p>3 pores all the way across it, you and I can agree</p> <p>4 that that's a lot more than 1 centimeter wide;</p> <p>5 correct.</p> <p>6 MR. CARTMELL: Object to the form.</p> <p>7 A. Again, I can't say. I just don't</p> <p>8 know. I'm saying I don't know what it is. I'm</p> <p>9 not disagreeing with you. I just don't know.</p> <p>10 Q BY MR. SNELL: There's no sheath on</p> <p>11 that mesh; correct?</p> <p>12 A. That is correct.</p> <p>13 Q. And there's certainly no trochars</p> <p>14 connected to it; correct?</p> <p>15 A. That is correct.</p> <p>16 Q. And you don't know how that --</p> <p>17 whatever mesh it was stretched; is that correct?</p> <p>18 A. I'd have to go back to the original</p> <p>19 document and see what they said.</p> <p>20 Q. Okay. Are you aware of any studies</p> <p>21 that have looked at potential shrinkage with the</p> <p>22 TVT device in the application of stress</p> <p>23 incontinence treatment that report that there was</p> <p>24 no shrinkage with the TVT?</p> <p>25 A. We'd have to go to the contraction</p>	<p>1 A. That's correct. On page 21 of my</p> <p>2 report.</p> <p>3 Q. You know Vypro was assessed even for</p> <p>4 the application of prolapse and was found to have</p> <p>5 a greater than 10 percent exposure rate; right?</p> <p>6 A. That is correct. But it was less than</p> <p>7 the existing Gynemesh.</p> <p>8 Q. Actually it was assessed and it was</p> <p>9 found to be 17 percent and Dr. Jacquetin found</p> <p>10 that it was not tolerated by the body.</p> <p>11 A. Okay.</p> <p>12 Q. Is that correct?</p> <p>13 A. I don't recall that. I have no reason</p> <p>14 to doubt that it's incorrect.</p> <p>15 Q. Okay. And the ULTRAPRO, you're aware</p> <p>16 that that was ultimately put into the Prolift</p> <p>17 Plus, and there were mesh exposures with that mesh</p> <p>18 in the POP application; correct?</p> <p>19 MR. CARTMELL: Object to the form. Go</p> <p>20 ahead.</p> <p>21 A. Yes. Again, and that reinforces my</p> <p>22 opinion. Mesh should not be placed in the vagina.</p> <p>23 Can we just -- I'm sorry to</p> <p>24 interrupt -- deflect the curtain the opposite</p> <p>25 direction. Thank you. Feel like God there for a</p>

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<p>1 second; I was glowing.</p> <p>2 Q BY MR. SNELL: You know that</p> <p>3 Dr. Jacquetin in the TVM group assessed Vypro in</p> <p>4 the transvaginal mesh pelvic organ prolapse</p> <p>5 application?</p> <p>6 A. That is correct. I've read that, yes.</p> <p>7 Q. And they found that tolerance of that</p> <p>8 material was poor?</p> <p>9 MR. CARTMELL: Object to the form.</p> <p>10 You got the study. Show it to him. I think -- I</p> <p>11 think you're misstating the study.</p> <p>12 Q BY MR. SNELL: You're aware of that;</p> <p>13 correct?</p> <p>14 A. I am aware that they did look at it.</p> <p>15 I am not aware of the specific details of that</p> <p>16 study. It's been a while since I looked at that</p> <p>17 study.</p> <p>18 Q. I have it here on the computer.</p> <p>19 A. That's fine. Which name or title is</p> <p>20 it? Or who's the lead author?</p> <p>21 Q BY MR. SNELL: Denis, D-e-n-i-s.</p> <p>22 A. Okay.</p> <p>23 Q. Denis, Jacquetin. Here you better --</p> <p>24 okay. You need to maximize -- there you go?</p> <p>25 A. Oh, so it's an abstract.</p>	<p>1 Q. And they talk about the use of a half</p> <p>2 absorbable mesh does not seem to reduce</p> <p>3 inflammation and could even accentuate it;</p> <p>4 correct?</p> <p>5 A. That's correct. All right. And then</p> <p>6 they go on to say, "Good results of the TVT does</p> <p>7 not seem to be much modified by the additional" --</p> <p>8 okay. That's separate.</p> <p>9 Q. Your understanding --</p> <p>10 A. I have to see if that Vypro -- they</p> <p>11 mentioned a bioabsorbable, is if they have Vicryl</p> <p>12 in there --</p> <p>13 Q. Right.</p> <p>14 A. -- or a collagen base of some sort.</p> <p>15 That's associated with increased inflammation.</p> <p>16 MR. CARTMELL: Hey, put the name of</p> <p>17 that study and the citation to it on the record,</p> <p>18 please.</p> <p>19 MR. SNELL: Yeah. Denis, D-e-n-i-s,</p> <p>20 Abstract 620. It was an abstract presentation.</p> <p>21 And Dr. Jacquetin there, too. All of the study</p> <p>22 subjects coming out of Clermont-Ferrand. Abstract</p> <p>23 620 at the joint ICS/IUGA 2004 conference in</p> <p>24 Paris, France. I'll make that representation. I</p> <p>25 know that's where this is from.</p>
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<p>1 Q. Right.</p> <p>2 A. Okay.</p> <p>3 Q. You see that they reported the</p> <p>4 tolerance was poor?</p> <p>5 A. Let me go to their conclusions.</p> <p>6 Q. Can I come around and look at it with</p> <p>7 you.</p> <p>8 A. By all means.</p> <p>9 Q. Because it's electronic, just so the</p> <p>10 record reflects -- it says in this study that</p> <p>11 tolerance of the Vypro mesh is VERY poor; correct?</p> <p>12 A. That's what it states, yes.</p> <p>13 Q. High rate of erosion, and problems of</p> <p>14 cicatrisation have been observed.</p> <p>15 A. Correct. C-i-c-a-t-r-i-s-a-t-i-o-n,</p> <p>16 which just means scars.</p> <p>17 Q. Okay.</p> <p>18 A. Contraction.</p> <p>19 Q. And it also had complications of</p> <p>20 retraction and rigidity were observed with the</p> <p>21 Vypro mesh?</p> <p>22 A. That is correct.</p> <p>23 Q. Frequently with clinical severe</p> <p>24 consequences; correct?</p> <p>25 A. That is correct.</p>	<p>1 THE DEPONENT: And I was at that</p> <p>2 meeting.</p> <p>3 Q BY MR. SNELL: Did you see this</p> <p>4 presentation?</p> <p>5 A. I don't recall seeing it, no.</p> <p>6 Q. And you know the Vypro mesh, it's a</p> <p>7 larger pore mesh than the mesh used in the TVT</p> <p>8 device; correct?</p> <p>9 A. It is.</p> <p>10 Q. And the Vypro mesh uses a combination</p> <p>11 of Vicryl with the Prolene polypropylene; correct?</p> <p>12 A. Again, I'd have to refresh my memory.</p> <p>13 That is my recollection. It is partially</p> <p>14 absorbable.</p> <p>15 Q. All right. The Vicryl part is what</p> <p>16 absorbs over time?</p> <p>17 A. That is correct.</p> <p>18 Q. And the Prolene polypropylene mesh is</p> <p>19 what's left behind; correct?</p> <p>20 A. That is the permanent portion of the</p> <p>21 implant, yes.</p> <p>22 MR. SNELL: Let's mark this.</p> <p>23 (Exhibit 24 marked.)</p> <p>24 Q BY MR. SNELL: Exhibit 24 is a study</p> <p>25 of various meshes, fascia, animal, cadaveric</p>

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<p>1 materials, and the rabbit model with implications</p> <p>2 for sling surgery; correct?</p> <p>3 A. That is correct.</p> <p>4 Q. This is a paper you were one of the</p> <p>5 authors of; correct?</p> <p>6 A. I was the lead author.</p> <p>7 Q. Okay. And this was published in the</p> <p>8 Journal of Urology?</p> <p>9 A. Correct. In 2004.</p> <p>10 Q. All right. Is the Journal of</p> <p>11 Urology -- does it have a poor peer review</p> <p>12 process?</p> <p>13 A. A poor, meaning incompetent? I</p> <p>14 mean --</p> <p>15 Q. Okay.</p> <p>16 A. As opposed to pore, p-o-r-e? You're</p> <p>17 talking poor, p-o-o-r?</p> <p>18 Q. Yes, sir, p-o-o-r.</p> <p>19 A. No. It would -- in urology, it is</p> <p>20 probably one of the most strict peer review, along</p> <p>21 with the European Urology Journal.</p> <p>22 Q. All right. So among the various</p> <p>23 things assessed, one was polypropylene mesh.</p> <p>24 Another was autologous fascia; correct?</p> <p>25 A. That is correct. And it was the Sparc</p>	<p>1 However, in the first 10 patients we didn't know</p> <p>2 the tensioning of this. No one had ever done it</p> <p>3 before. And so we're accounting for a lot of</p> <p>4 different factors. Is it going to -- is it going</p> <p>5 to tighten up or is it going to stretch out. We</p> <p>6 didn't know.</p> <p>7 Q. Okay.</p> <p>8 A. And that's why it's a feasibility</p> <p>9 study.</p> <p>10 Q. Okay. The last page you talk about</p> <p>11 "the polypropylene mesh has extremely low</p> <p>12 stiffness at baseline, but it demonstrated</p> <p>13 increasing stiffness with time. This phenomenon</p> <p>14 is likely caused by the ingrowth of tissues into</p> <p>15 the interstices of the mesh."</p> <p>16 A. That's correct. That's what we</p> <p>17 stated.</p> <p>18 Q. Is that an accurate statement?</p> <p>19 A. That is an accurate statement of what</p> <p>20 we found. We did not know at that point in time</p> <p>21 the potential implications of that.</p> <p>22 Q. You concluded that the biomechanical</p> <p>23 results of the current study support the use of</p> <p>24 polypropylene mesh for sling surgery relative to</p> <p>25 other non-autologous materials; right?</p>
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<p>1 that we used.</p> <p>2 Q. And Sparc was a -- that was a</p> <p>3 monofilament polypropylene mesh; correct?</p> <p>4 A. Correct. Quite similar to TVT.</p> <p>5 Q. And there was a rapid loss of strength</p> <p>6 and stiffness in the porcine and cadaveric</p> <p>7 materials; correct?</p> <p>8 A. That is correct.</p> <p>9 Q. And the autologous fascia, as well as</p> <p>10 small intestinal submucosa demonstrated the</p> <p>11 highest rate of contraction; correct?</p> <p>12 A. In this short-term limited, yes,</p> <p>13 that's what we found.</p> <p>14 Q. Does the autologous fascia contract in</p> <p>15 the human body?</p> <p>16 A. It is reabsorbed. And remodeled is</p> <p>17 the term we usually use. As opposed to</p> <p>18 contraction.</p> <p>19 Q. I saw in your pilot study with the</p> <p>20 10 patients with the transobturator autologous</p> <p>21 sling that you reported that you placed that sling</p> <p>22 loosely in order to hopefully minimize contraction</p> <p>23 of the autologous tissues.</p> <p>24 Do you recall that statement?</p> <p>25 A. I don't recall that statement per se.</p>	<p>1 A. Again, that's what we stated as of</p> <p>2 2004 in our short-term study because we found the</p> <p>3 increased stiffness and thought that that would be</p> <p>4 increased as far as efficacy. And we didn't</p> <p>5 realize that that process continues.</p> <p>6 Q. You published a subsequent study in</p> <p>7 follow-up; correct?</p> <p>8 A. Correct. By Krambeck, et al.</p> <p>9 MR. SNELL: Go off the record for a</p> <p>10 second.</p> <p>11 (Exhibit 25 marked.)</p> <p>12 Q BY MR. SNELL: So-Exhibit 25, Doctor,</p> <p>13 is your follow-up study that you published in 2006</p> <p>14 in the Urology Journal; correct?</p> <p>15 A. Correct.</p> <p>16 Q. And this was a study where you found</p> <p>17 significant differences were found for</p> <p>18 inflammation, eosinophil infiltrate and</p> <p>19 inflammatory rind at 12 weeks with polypropylene</p> <p>20 mesh having the lowest degree; correct?</p> <p>21 A. That was one of our findings.</p> <p>22 Q. And that was a study looking at</p> <p>23 polypropylene mesh versus cadaveric fascia,</p> <p>24 porcine dermis, porcine small intestine submucosa,</p> <p>25 and autologous fascia; correct?</p>

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<p>1 A. Those were all the properties or the</p> <p>2 substances we studied.</p> <p>3 Q. All right. And you reported that the</p> <p>4 inflammation with the cadaveric fascia and porcine</p> <p>5 may cause rapid clinical deterioration compared to</p> <p>6 the autologous fascia and polypropylene mesh?</p> <p>7 A. That is correct. That was the main</p> <p>8 purpose of this study, looking at what happens to</p> <p>9 the cadaveric and porcine materials. Does the</p> <p>10 body rapidly absorb them, which we found out it</p> <p>11 did. And the polypropylene had the greatest</p> <p>12 degree of scar formation.</p> <p>13 Q. And that's one of the reasons why</p> <p>14 cadaveric fascia and porcine materials for use in</p> <p>15 the sling application never really caught on to a</p> <p>16 large degree because, with longer term follow-up</p> <p>17 surgeons found that those slings would actually be</p> <p>18 absorbed into the body; correct?</p> <p>19 A. Partly correct. The porcine, no</p> <p>20 question. The porcine dermis and then the porcine</p> <p>21 SIS, in my opinion, were horrible products. I</p> <p>22 used them and they failed miserably. It was</p> <p>23 worthless to do that. Actually worse than</p> <p>24 worthless.</p> <p>25 The -- I forget the rest of what your</p>	<p>1 incorrect with that. We had our facts right, our</p> <p>2 conclusion wrong.</p> <p>3 Q. You wrote that the facial slings using</p> <p>4 harvested autologous fascia which increases</p> <p>5 operative time and patient morbidity.</p> <p>6 And that's true as of today; correct?</p> <p>7 A. I would not disagree with that.</p> <p>8 Q. And you report other studies have</p> <p>9 shown a decrease in tensile strength of cadaveric</p> <p>10 fascia; correct?</p> <p>11 A. Correct. But the issue was -- we</p> <p>12 assumed at that point in time that increasing</p> <p>13 tensile strength was a good thing. We're now</p> <p>14 realizing that the pelvis and the vagina are</p> <p>15 elastic and have to bend, and so we're not</p> <p>16 necessarily agreeing with the conclusions I had in</p> <p>17 this study.</p> <p>18 Q. You found that the xenograft and</p> <p>19 cadaveric products demonstrated high degrees of</p> <p>20 inflammatory infiltrate; correct?</p> <p>21 A. That is correct. Specifically with</p> <p>22 the SIS. And those had a significant immune</p> <p>23 response to it. Yes. And those are not used in</p> <p>24 our practice at all anymore because of that.</p> <p>25 Q. Okay. What is the significance of the</p>
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<p>1 statements were. But the --</p> <p>2 Q. Cadaveric. With regard to the</p> <p>3 cadaveric.</p> <p>4 A. And the cadaveric -- there's multiple</p> <p>5 different types of cadaveric and how they are</p> <p>6 processed. And some are good and some are not</p> <p>7 good. The one we found here raised questionable</p> <p>8 results.</p> <p>9 Q. How do you know which ones are good</p> <p>10 and not good until you try them?</p> <p>11 A. That's a major problem, but pretty</p> <p>12 much agreed upon, freeze died irradiated cadaverics</p> <p>13 have a higher -- not degradation. Decomposition.</p> <p>14 De --</p> <p>15 Q. The irradiation process that you need</p> <p>16 to do to cadaveric tissue to reduce any potential</p> <p>17 transmission of disease is known to cause those</p> <p>18 materials to degrade; correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you wrote here that the fibrosis</p> <p>21 and scarring noted with the polypropylene mesh may</p> <p>22 also contribute to a more lasting repair; correct?</p> <p>23 A. You're correct. That was at that</p> <p>24 point in time the conclusions that we reached.</p> <p>25 And we subsequently discovered that we were</p>	<p>1 SIS for the porcine? Is that a single incision</p> <p>2 sling?</p> <p>3 A. No. It's just like -- instead of</p> <p>4 using cadaveric tissue for the sling, we use SIS,</p> <p>5 which is pig intestine, submucosal pig intestines.</p> <p>6 There's also porcine dermis, but both of them</p> <p>7 contain porcine DNA and are not recommended to be</p> <p>8 used.</p> <p>9 Q. And you're right. "We also noted a</p> <p>10 low degree of inflammation with polypropylene mesh</p> <p>11 compared to the other materials."</p> <p>12 A. Yes. And that's a relative statement</p> <p>13 in the short-term in the rabbit model compared to</p> <p>14 the processes that we know create a significant</p> <p>15 amount of immune response because they still have</p> <p>16 porcine DNA. So there's a major foreign body</p> <p>17 reaction to that.</p> <p>18 Q. And you found that there was a low</p> <p>19 degree of inflammation with polypropylene mesh,</p> <p>20 which was similar to what was seen with the</p> <p>21 autologous fascia; correct?</p> <p>22 A. Correct. In the short-term that is</p> <p>23 correct. That's what we found.</p> <p>24 Q. And so the polypropylene mesh in your</p> <p>25 study acted most closely to the autologous fascia;</p>

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<p>1 correct?</p> <p>2 A. Correct. In the rabbit model, placed</p> <p>3 transabdominally, that is the conclusions we</p> <p>4 reached in 2008.</p> <p>5 Q. All right. I mean, some of the</p> <p>6 studies you cite to are in dogs and other animals</p> <p>7 that are not even in the sling application like</p> <p>8 you tried to do; right?</p> <p>9 A. I agree.</p> <p>10 Q. So are you saying that your study is</p> <p>11 not important, or that --</p> <p>12 A. No.</p> <p>13 Q. -- the findings are inaccurate?</p> <p>14 A. No. I'm saying it has to be looked at</p> <p>15 as far as -- this is looking what the rabbit model</p> <p>16 does to these various different slings in the</p> <p>17 short-term. I think they're very important</p> <p>18 findings.</p> <p>19 Q. You say, our results -- "the</p> <p>20 alternatives to biologic material, synthetics are</p> <p>21 gaining popularity. The polypropylene mesh has</p> <p>22 shown promising initial and long-term results</p> <p>23 similar to that of autologous sling material";</p> <p>24 correct?</p> <p>25 A. Correct.</p>	<p>1 Q. You say UCLA State of the Art Urology</p> <p>2 Meeting --</p> <p>3 A. Oh. Oh.</p> <p>4 Q. -- page 4.</p> <p>5 A. That's a yearly meeting that they have</p> <p>6 that Raz and other experts discuss. That was an</p> <p>7 attendance-only meeting. That's not Grand Rounds.</p> <p>8 Q. Okay. I'm sorry.</p> <p>9 A. No.</p> <p>10 Q. Were you just kind of -- were you</p> <p>11 identifying different conferences or meetings you</p> <p>12 go to typically?</p> <p>13 A. Correct. That was continuing medical</p> <p>14 education.</p> <p>15 Q. Okay.</p> <p>16 A. Where specifically UCLA is well-known</p> <p>17 for having Dr. Raz there. So there's always a</p> <p>18 strong female urology section to it. That's all</p> <p>19 that's stating.</p> <p>20 Q. Dr. Raz is one of the proponents of</p> <p>21 needle suspension procedures over the years;</p> <p>22 correct?</p> <p>23 A. Well, he used to be. He's not</p> <p>24 anymore. He doesn't do his own procedure anymore.</p> <p>25 Q. Why not?</p>
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<p>1 Q. And then you go on to say, "Our</p> <p>2 results indicated little degree of inflammation</p> <p>3 and significant fibrosis similar to that with</p> <p>4 autologous material"; correct?</p> <p>5 A. Correct. And that is the significant</p> <p>6 finding of that, which we did not correctly</p> <p>7 interpret our results at that point in time.</p> <p>8 Q. Well, you've stated significantly that</p> <p>9 none of the material appeared grossly infected at</p> <p>10 explantation in your study either; is that right?</p> <p>11 A. That's correct. In the rabbit model</p> <p>12 placed transabdominally, that is correct.</p> <p>13 Q. All right. I think in your report</p> <p>14 somewhere you mentioned -- and maybe I'm</p> <p>15 misstating this, but you were relying on -- or you</p> <p>16 found something important coming out of the UCLA</p> <p>17 Grand Rounds?</p> <p>18 A. No. No. I don't recall that.</p> <p>19 Q. Okay.</p> <p>20 A. I attended multiple UCLA meetings</p> <p>21 which involved discussions of meshes, but I think</p> <p>22 that's the only thing I could --</p> <p>23 Q. Okay.</p> <p>24 A. I don't think I ever attended what we</p> <p>25 call Grand Rounds.</p>	<p>1 A. Didn't work.</p> <p>2 Q. Okay. Do you have that Ford Cochrane</p> <p>3 Review you cited to in your expert report handy?</p> <p>4 I think it was one of the first exhibits we</p> <p>5 marked. Can I just turn to a page. I have a</p> <p>6 question for you.</p> <p>7 With the 2.1 percent mesh exposure</p> <p>8 rate they saw with the retropubic sling in the</p> <p>9 Ford Cochrane Review of 2015, would there be a</p> <p>10 scientifically reliable way of stating which, if</p> <p>11 any, of those exposures occurred due to the</p> <p>12 mechanically cut nature of the mesh?</p> <p>13 A. You have to look at those studies and</p> <p>14 see when they were published. If they're</p> <p>15 published prior to 2007, you could say all of them</p> <p>16 were attributed. If they're published after that</p> <p>17 we don't know, and they'd have to look at the</p> <p>18 studies, see if they break it down in mechanical</p> <p>19 versus laser.</p> <p>20 Q. Do any of the randomized control</p> <p>21 trials report that there was a sawing effect with</p> <p>22 the TVT mechanically cut mesh in the treatment of</p> <p>23 stress incontinence?</p> <p>24 A. I have not seen that in the</p> <p>25 literature. That is based upon my personal</p>

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<p>1 experience with Sparc, not the TVT, and then also</p> <p>2 internal documentation.</p> <p>3 Q. So if there was a 2.1 percent rate --</p> <p>4 if there was a 2.1 percent rate of exposure with</p> <p>5 the retropubic TVT sling -- and I want you to</p> <p>6 assume that all of those were mechanically cut,</p> <p>7 okay -- how would you scientifically, reliably</p> <p>8 ascertain which of those 21 patients' exposures</p> <p>9 were because of the mechanical cut nature of the</p> <p>10 mesh?</p> <p>11 A. Looking at this, I have no idea how</p> <p>12 many of these are TVT or not. It says retropubic</p> <p>13 slings, but that could be anything. It's not</p> <p>14 talking up-down, top-down, or anything. They're</p> <p>15 not comparing TVT right here necessarily.</p> <p>16 So based upon that, I don't know how</p> <p>17 to answer your question because I don't know what</p> <p>18 they're looking at, because they just say</p> <p>19 retropubic.</p> <p>20 Q. You didn't look and see how many of</p> <p>21 those studies were the TVT study?</p> <p>22 A. I did not look through those to find</p> <p>23 out that information, no.</p> <p>24 Q. So let me ask you this hypothetical</p> <p>25 then. If there were hypothetically 21 mesh</p>	<p>1 A. Correct.</p> <p>2 Q. That study didn't assess the TVT</p> <p>3 retropubic mid-urethral sling to treat stress</p> <p>4 incontinence; correct?</p> <p>5 A. Correct. It was TVT-Secur versus the</p> <p>6 TVTO.</p> <p>7 Q. And the TVTO, in that study, do you</p> <p>8 recall if there were any mesh exposures?</p> <p>9 A. I'd have to look at the study. I</p> <p>10 don't recall.</p> <p>11 Q. Do you know if that TVTO mesh was</p> <p>12 mechanical cut?</p> <p>13 A. The Secur was laser cut. And it was</p> <p>14 my understanding that the TVTO was mechanically</p> <p>15 cut.</p> <p>16 Q. And the TVTO mechanically cut had a</p> <p>17 lower rate of exposure than the TVT-Secur;</p> <p>18 correct?</p> <p>19 MR. CARTMELL: Tell him, if you know.</p> <p>20 A. Again, I do not know. I'd have to</p> <p>21 look at the study.</p> <p>22 Q. BY MR. SNELL: Are there any data in</p> <p>23 women on the TVT used to treat stress incontinence</p> <p>24 which report how many, if any, of those TVT</p> <p>25 mechanically cut slings have a sawing effect?</p>
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<p>1 exposures out of 1,000 TVT mechanically cut</p> <p>2 retropubic device cases, how would you -- would</p> <p>3 you be able to scientifically reliably say which</p> <p>4 of those 21 exposures were due to the mechanical</p> <p>5 cut nature of the mesh? And if so, how did you do</p> <p>6 that?</p> <p>7 A. In a retrospective fashion, you would</p> <p>8 not be able to determine that with precision. You</p> <p>9 could say it's going to be a contributing factor</p> <p>10 in certain numbers. Also contributing could be</p> <p>11 degradation, infection, subclinical infection, all</p> <p>12 those things. In a retrospective fashion, you</p> <p>13 cannot. That's why it has to be done</p> <p>14 prospectively.</p> <p>15 Q. And as you sit here today, you have</p> <p>16 never seen, in any prospective TVT retropubic</p> <p>17 study, any author attribute clinical mesh exposure</p> <p>18 due to a sawing of the mesh; correct?</p> <p>19 A. I'd only have to go off of data on</p> <p>20 TVT-Secur and TVT -- TOT, the Hinoul study, but</p> <p>21 that is not a TVT study. To the best of my</p> <p>22 knowledge, that has not been evaluated. It should</p> <p>23 have been, but it has not been evaluated.</p> <p>24 Q. The TVT-Secur, that was the laser cut</p> <p>25 mesh; correct?</p>	<p>1 A. To the best of my knowledge, in those,</p> <p>2 they did not use that specific terminology. The</p> <p>3 fraying and the sawing is more from internal</p> <p>4 documentation of complaints coming into Ethicon</p> <p>5 and their discussions about it.</p> <p>6 Q. Do any of the clinical studies on TVT</p> <p>7 used to treat stress incontinence report the mesh</p> <p>8 frame and its use in women?</p> <p>9 A. Again, just like the last answer, I am</p> <p>10 unaware of any manuscript that discusses that</p> <p>11 specific terminology. That comes from internal</p> <p>12 documentation and also comes from my experience</p> <p>13 with the TVT, which did the same thing. But I</p> <p>14 didn't write on that either.</p> <p>15 Q. Have you ever seen any scientifically</p> <p>16 reliable studies in women that document the</p> <p>17 incidents at which there is -- withdrawn.</p> <p>18 I just didn't remember the word. You</p> <p>19 used two words, and I wanted to use one of them.</p> <p>20 Have you ever seen any scientifically</p> <p>21 reliable studies in women utilizing the TVT</p> <p>22 retropubic device to treat incontinence that</p> <p>23 states the incidence of fraying of the mesh?</p> <p>24 A. Again, this is -- what I stated</p> <p>25 before. I've not seen that in the literature,</p>

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<p>1 that specific terminology used. That comes from</p> <p>2 the internal documents and complaints that came</p> <p>3 in.</p> <p>4 Q. Do you know the incidence for which</p> <p>5 fraying of TVT retropubic mesh in the treatment of</p> <p>6 stress incontinence occurs?</p> <p>7 A. We have to go to my report on page 21,</p> <p>8 where I talk about fraying --</p> <p>9 Q. Um-hum.</p> <p>10 A. -- and particle loss, and the sawing</p> <p>11 effect. And the incidence -- okay. It varies --</p> <p>12 as you go through the various sections here in the</p> <p>13 report on that.</p> <p>14 Say on page 22, testing done by</p> <p>15 Ethicon. So that after elongation, 18 percent of</p> <p>16 the weight was lost due to particle loss.</p> <p>17 Pariente says the point -- 8.5 percent of the</p> <p>18 particle loss.</p> <p>19 Q. But my question is specific to</p> <p>20 fraying. So what --</p> <p>21 A. Fraying?</p> <p>22 Q. Yes, sir. What -- I'm sorry. Yes,</p> <p>23 Doctor.</p> <p>24 What's the incidence of fraying that</p> <p>25 occurs? I didn't see that number in your report.</p>	<p>1 obstruction, and then what happened to those</p> <p>2 individuals.</p> <p>3 Q. What types of slings were those?</p> <p>4 A. Those were all types of slings.</p> <p>5 Retropubic, suprapubic, transobturator, and</p> <p>6 vaginal.</p> <p>7 Q. Were there any retropubic TVTs in that</p> <p>8 study?</p> <p>9 A. I'd have to look and see what we</p> <p>10 documented.</p> <p>11 Q. What was the main result of that</p> <p>12 study? What percent of the patients remained</p> <p>13 continent following sling release.</p> <p>14 A. Again, I'd have to look at that study,</p> <p>15 the exact numbers on it.</p> <p>16 Q. Do you have it with you?</p> <p>17 A. Yes, I do. I should. Actually I</p> <p>18 don't have the paper. I would have to guess on</p> <p>19 the numbers. It was a high -- the issue was --</p> <p>20 MR. CARTMELL: Don't guess. If you</p> <p>21 know, you know.</p> <p>22 A. All I'll say is there's a high rate of</p> <p>23 reoperation once we cut the sling over time. That</p> <p>24 was the significant findings.</p> <p>25 Q BY MR. SNELL: What do you mean by</p>
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<p>1 A. I don't think I state a specific</p> <p>2 number in there. However, during the placement of</p> <p>3 it, where, you know, they talk about 50 percent of</p> <p>4 these devices are elongated during the</p> <p>5 implantation with 12 pounds of force, that causes</p> <p>6 the -- to rope, fray, and particle loss. So I</p> <p>7 can't give you an exact percentage. But it is a</p> <p>8 constellation of problems that happen with that.</p> <p>9 Q. Other than your paper on the use of</p> <p>10 the Holmium laser, have you published on treating</p> <p>11 any mesh complications?</p> <p>12 A. Yes.</p> <p>13 Q. Where? What paper would that be? For</p> <p>14 stress urinary incontinence?</p> <p>15 A. Stress urinary incontinence.</p> <p>16 Q. Yes.</p> <p>17 A. I have the copy of my CV, which is an</p> <p>18 exact copy of yours.</p> <p>19 My page 17 of 25, I have the Holmium</p> <p>20 laser complication, as you mentioned. And then</p> <p>21 number 9 on this is Clifton, et al., where I'm the</p> <p>22 senior author, of Repeat Anti-Incontinence</p> <p>23 Procedures Following a Sling Release.</p> <p>24 So that's a study of individuals who</p> <p>25 had obstruction following a sling. We treated the</p>	<p>1 that?</p> <p>2 A. What I mean is the traditional thought</p> <p>3 was, based upon a Webster paper, George Webster</p> <p>4 out of Duke, is that if you cut slings, 85 percent</p> <p>5 of people stayed dry. But the problem is no one</p> <p>6 had followed those individuals long-term. So we</p> <p>7 followed them long-term and found out that over</p> <p>8 time the rate of incontinence increased, requiring</p> <p>9 further treatment. So bottom line, it's not like</p> <p>10 if you obstruct somebody, you treat it, they're</p> <p>11 done. They're great. No, they have problems</p> <p>12 later.</p> <p>13 Q. What was the mean time for your</p> <p>14 surgery to release the sling?</p> <p>15 A. I'd have to look at the paper.</p> <p>16 Q. Was it more than a year or less than a</p> <p>17 year?</p> <p>18 A. I'd have to look at the paper. I</p> <p>19 don't recall and I don't, for some reason, have a</p> <p>20 copy of it here.</p> <p>21 Q. What was the long-term follow-up that</p> <p>22 you say that you all conducted? How long was</p> <p>23 that?</p> <p>24 A. Again, that's what I'm saying. I need</p> <p>25 to see the paper because I can't recall what the</p>

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<p style="text-align: right;">Page 310</p> <p>1 duration was.</p> <p>2 Q. As you sit here today, do you know</p> <p>3 whether 50 percent or more -- strike that.</p> <p>4 As sit here today, was it more likely</p> <p>5 than not that those papers who had a sling release</p> <p>6 would not require reoperation for incontinence?</p> <p>7 A. I'll get the paper.</p> <p>8 Q. Okay.</p> <p>9 A. Because I can't recall.</p> <p>10 Q. That's fine. I don't think I have it.</p> <p>11 So if you don't remember, that's fine.</p> <p>12 MR. CARTMELL: You don't need to get</p> <p>13 the paper.</p> <p>14 MR. SNELL: It would be good if he got</p> <p>15 the paper. But that's fine. If he doesn't</p> <p>16 remember his own data, that's fine. I'm not</p> <p>17 trying to trick him. I just want to know.</p> <p>18 MR. CARTMELL: I mean, if you don't</p> <p>19 know the answer, then say you don't know, okay.</p> <p>20 A. I don't know the exact number. We</p> <p>21 worked hard on it, and to do it justice, I'd have</p> <p>22 to find the paper.</p> <p>23 Q BY MR. SNELL: Fair enough.</p> <p>24 In your Holmium laser paper, the</p> <p>25 majority of women got better; right?</p>	<p style="text-align: right;">Page 312</p> <p>1 off the record while he reviews it.</p> <p>2 MR. SNELL: It's his own paper. So</p> <p>3 you're going to waste my -- you're going to burn</p> <p>4 my time with him looking at his own paper?</p> <p>5 MR. CARTMELL: You wanted him to look</p> <p>6 at it. This is your time, period.</p> <p>7 Q. BY MR. SNELL: Okay. Doctor, could</p> <p>8 you quickly look at your own paper that you wrote?</p> <p>9 A. 14 percent of patients after a sling</p> <p>10 release ultimately went on to a repeat operation.</p> <p>11 That's what we had in our data.</p> <p>12 Q. All right. So that means 86 percent</p> <p>13 of those patients did not go on to a repeat sling</p> <p>14 operation?</p> <p>15 A. Yes. But some of those elected not to</p> <p>16 because they were scared from previous surgeries.</p> <p>17 Q. What percentage of the patients</p> <p>18 elected not to?</p> <p>19 A. I'd have to look at the study. I</p> <p>20 don't have that. So I mean, that's -- again, I'd</p> <p>21 have to look at the study.</p> <p>22 Q. Fair enough.</p> <p>23 When you do your autologous fascial</p> <p>24 slings, and the transobturator autologous slings,</p> <p>25 how do you tension those slings?</p>
<p style="text-align: right;">Page 311</p> <p>1 A. At this point. But we are still</p> <p>2 continuing to follow those, and that's what was</p> <p>3 raised in the SUFU lecture when I talked about</p> <p>4 this. We don't know what's going to happen to</p> <p>5 these people long-term.</p> <p>6 Q. Here, I have your paper. We have it</p> <p>7 here. Clifton, you said?</p> <p>8 A. Clifton.</p> <p>9 Q. This says median follow-up after</p> <p>10 release was 32 months. Of the 93 patients,</p> <p>11 14 percent required repeat anti-incontinence</p> <p>12 procedure after sling realize.</p> <p>13 A. Okay. All right.</p> <p>14 Q. That's your paper; right?</p> <p>15 A. I can't see the top of it. I'll</p> <p>16 assume you're telling me the truth, though.</p> <p>17 That's it. Yes.</p> <p>18 Q. All right. So actually, your data</p> <p>19 were consistent with other data in the literature,</p> <p>20 because 86 percent of your patients didn't require</p> <p>21 repeat anti-incontinence procedure; right?</p> <p>22 A. I'll have to see the paper.</p> <p>23 MR. SNELL: We can go off the record</p> <p>24 while he reviews that.</p> <p>25 MR. CARTMELL: No. We're not going</p>	<p style="text-align: right;">Page 313</p> <p>1 A. How do I tension them? I -- well, you</p> <p>2 said two different things. Pubovaginal or</p> <p>3 autologous transobturator. Which one?</p> <p>4 Q. Either one. Or if there's a</p> <p>5 difference, just tell me there's a difference.</p> <p>6 A. Well, there's a difference between the</p> <p>7 two.</p> <p>8 Q. Fair enough. How do you tension</p> <p>9 autologous fascial slings?</p> <p>10 A. Well, again, there's two different</p> <p>11 types. Pubovaginal or transobturator?</p> <p>12 Q. Pubovaginal?</p> <p>13 A. Pubovaginal, there's three steps to do</p> <p>14 this. Place a cystoscope in the urethra, deflect</p> <p>15 it 15 degrees. Up top in the abdomen, you tie</p> <p>16 initial knot that you can fit two finger breadths</p> <p>17 in it. Secure it with a clamp. Tie multiple</p> <p>18 knots. In doing that, you're fairly reproducible</p> <p>19 as far as the tension goes.</p> <p>20 Q. Some surgeons use one finger breadth;</p> <p>21 correct?</p> <p>22 A. It's -- you can -- yeah. Well, I</p> <p>23 can't speak to that. I do two finger breadths and</p> <p>24 it works.</p> <p>25 Q. Is that because that's how you were</p>



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<p>1 taught to do that procedure?</p> <p>2 A. Yeah, but I'm going to modify it.</p> <p>3 That's originally how -- oh, I was taught the</p> <p>4 leave a gap. The key is you leave it loose.</p> <p>5 Q. Okay.</p> <p>6 A. And so if you use one finger breadth</p> <p>7 or two finger breadths might not make all that</p> <p>8 difference because it's the distance from the</p> <p>9 fascia to your knot, not necessarily the width.</p> <p>10 So one finger breadth and two finger breadths is</p> <p>11 actually going to be the same.</p> <p>12 Q. You don't really use any objective</p> <p>13 measurement to assess tension; correct?</p> <p>14 A. That is an objective. 15 degrees and</p> <p>15 one finger breadth. So I have objective,</p> <p>16 reproducible data. And I have never had, in my</p> <p>17 pubovaginal slings, a patient go into retention</p> <p>18 that was not a purposeful retention.</p> <p>19 Q. You don't use any type of gauge to</p> <p>20 assess tension on the sutures; correct?</p> <p>21 A. That does not exist for the</p> <p>22 pubovaginal slings.</p> <p>23 Q. All right. And is there any</p> <p>24 literature that reports on the effect, if any, of</p> <p>25 using one, two, or three suture finger breadths of</p>	<p>1 reproducible in my hands.</p> <p>2 Q. Right. But you don't do all the sling</p> <p>3 surgeries in this country. So I'm more interested</p> <p>4 in out in the masses in the United States.</p> <p>5 There is a fairly high rate of urinary</p> <p>6 retention following the autologous pubovaginal</p> <p>7 sling; right?</p> <p>8 MR. CARTMELL: Object and move to</p> <p>9 strike the statement of counsel. Object to the</p> <p>10 form as well.</p> <p>11 MR. SNELL: I'll withdraw the</p> <p>12 statement.</p> <p>13 Q BY MR. SNELL: Let me just -- looking</p> <p>14 broadly, nationally, okay, across the data, there</p> <p>15 is a fairly high rate of urinary retention</p> <p>16 following autologous pubovaginal slings; correct?</p> <p>17 MR. CARTMELL: Object to the form.</p> <p>18 A. I can't agree with that. You say</p> <p>19 fairly high. I don't know that. I've not seen</p> <p>20 that data.</p> <p>21 Q BY MR. SNELL: You've seen reports in</p> <p>22 the data of rates of retention higher than</p> <p>23 20 percent following autologous pubovaginal sling?</p> <p>24 A. It depends on how you're describing</p> <p>25 retention. If you're talking immediately</p>
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<p>1 detensioning for the autologous pubovaginal sling</p> <p>2 as opposed to some other method of tensioning?</p> <p>3 A. No, there's nothing in the literature</p> <p>4 like that. The teaching is to leave it loose.</p> <p>5 Q. And realizing you don't really do the</p> <p>6 Burch. Do you even remember how you were taught</p> <p>7 to tension or detension a Burch?</p> <p>8 A. No, I don't remember that.</p> <p>9 Q. What is wrong with the tensioning of</p> <p>10 the TVT retropubic device, if anything, in your</p> <p>11 opinion?</p> <p>12 A. It's not reproducible. The</p> <p>13 pubovaginal sling, I can tell somebody exactly</p> <p>14 like I told you. Cystoscope in, deflect it</p> <p>15 15 degrees, two finger breadths up, tie it loose,</p> <p>16 and you won't have retention.</p> <p>17 TVT, it says tension free, but then</p> <p>18 there's tension. And so it's not reproducible. I</p> <p>19 can't tell you how to tension it correctly. I can</p> <p>20 tell you the pubovaginal sling.</p> <p>21 Q. Well, with the pubovaginal sling,</p> <p>22 there is a fair number of patients who have</p> <p>23 urinary retention after that procedure; right?</p> <p>24 A. I can't speak to those. I can speak</p> <p>25 to my own experience. Like I say, it's</p>	<p>1 postoperatively, yes, that is very commonly.</p> <p>2 That's why a suprapubic tube or intermittent</p> <p>3 catheterization is not uncommonly required.</p> <p>4 Permanent retention after a month or six weeks,</p> <p>5 that's debatable, the duration, should be very</p> <p>6 low. In experienced people's hands, it's</p> <p>7 essentially zero. Again, my hands zero.</p> <p>8 Q. You've read the sister study by the --</p> <p>9 that was funded by the NIH that compared the</p> <p>10 autologous pubovaginal fascial sling to the Burch</p> <p>11 colposuspension, and they found statistically</p> <p>12 significant higher rates of not only voiding</p> <p>13 dysfunction and retention but retention requiring</p> <p>14 reoperation in the autologous sling arms; correct?</p> <p>15 A. That's been a long time since I've</p> <p>16 read it. I have to look at that paper. That was</p> <p>17 a good paper, but it's been a long time since I've</p> <p>18 seen it.</p> <p>19 MR. CARTMELL: I don't mean to</p> <p>20 interrupt, but I'd like to check the time, please.</p> <p>21 THE REPORTER: 7 hours and 13 minutes.</p> <p>22 MR. CARTMELL: Okay. You're done. If</p> <p>23 you want to go -- I may have a few questions. But</p> <p>24 if -- if -- we can go off the record if you want</p> <p>25 and talk about what you and Ben agreed to. It's</p>

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<p>1 just nobody told me that, and I really need to be 2 somewhere. 3 But let's go off the record right now. 4 MR. SNELL: Well, no. This needs to 5 be put on the record, and I have emails 6 documenting this, where Ben said, Burt, the MDL 7 design defect dep and New Jersey general TVT dep 8 have to done in one sitting on one day; you got to 9 do it today. And I said, okay, Ben, I will. And 10 then he and Judy Walberger, are doing the case 11 specific Watkins deposition next weekend. So that 12 was the agreement. 13 And I emailed Ben, fine, I'll do that. 14 No problem. I'll start the New Jersey general TVT 15 dep after this deposition, okay. And nobody ever 16 said that that wasn't going to occur. And I came 17 here with that expectation. And I wouldn't lie to 18 you. I mean, you've seen the email. Were you on 19 the email? It's in the email. 20 MR. CARTMELL: You don't have to 21 answer that. 22 MR. SNELL: You don't have to answer. 23 You're not under oath. 24 But with that said, what do you want 25 to do? I understand you have to do something with</p>	<p>1 idea. 2 MR. SNELL: Okay. Yeah, I mean, that 3 wasn't my idea, okay. One. 4 Two, I understand. I know -- you 5 know, look, I have a family, too, and I sympathize 6 for you. 7 But, three, I came here with that 8 intention and am ready to go. 9 And four, in New Jersey, my experts 10 have been deposed for pretty much more than 11 12 hours in a sitting. 12 (Recessed from 5:33 p.m. to 13 5:42 p.m.) 14 MR. SNELL: So I will pass the witness 15 in the MDL design defect case, and I reserve the 16 right to do the New Jersey TVT general deposition, 17 as I told Ben. 18 And I'm looking at my email that I 19 sent to him, where I said, "That's fine. I will 20 do my MDL design defect deposition first. And 21 after that we will do the New Jersey general TVT 22 deposition for anything that was not already 23 addressed." 24 I'll stand by that statement I sent to 25 Ben. I will not be duplicative. I really only</p>
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<p>1 your family. 2 MR. CARTMELL: We've been here nine 3 hours, and I don't want to put him through -- if 4 you told me you had 30 minutes or an hour, then 5 maybe, but I mean -- 6 MR. ROSENBLATT: Did they agree to 7 extend any deadline? Will that work? 8 MR. CARTMELL: What's the deadline in 9 New Jersey we're talking about? 10 MR. SNELL: I don't know. I think 11 it's October 5th or something. 12 MR. ROSENBLATT: I don't know. 13 MR. CARTMELL: Let me make a call, 14 okay. 15 MR. SNELL: Yeah. 16 MR. CARTMELL: I mean, I don't want to 17 get anybody in trouble and all that, and I get the 18 idea of having -- you know, doing them all at 19 once. But I'm telling you, I knew nothing about 20 this. And I think the idea of making a 21 deposition -- you know, he's been here 9 hours. 22 We've been on the record over 7 hours. That's 23 hard. I don't know that I want him to continue 24 this. 25 MR. ROSENBLATT: It wasn't Burt's</p>	<p>1 have the warning stuff from my quick review of his 2 report left over. So I am not foregoing my right 3 to do that portion. And I will make a statement 4 on the record that New Jersey, the deposition of 5 an expert is not limited to 7 hours. My experts 6 have been deposed in cases in New Jersey for well 7 over 10 hours. But so that's my position. And 8 I -- go ahead, Tom. 9 MR. CARTMELL: Okay. Just so it's 10 clear. We took a break. I called Ben. He told 11 me that the correspondence back and forth was -- 12 or our position, I guess, that he stated was you 13 needed to do both the New Jersey and the MDL 14 deposition today, meaning in 7 hours, because 15 there's a 7-hour requirement from the -- I'm just 16 telling you what he said, from the MDL. And that 17 the reports are the same. The general causation 18 reports. 19 You just pointed out to me that in 20 New Jersey there are failure-to-warn opinions that 21 you have not yet been able to question the witness 22 on. And I do agree with that. You have not done 23 that. 24 You've said you wanted to continue the 25 deposition for that. I had not been told -- and</p>

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<p>1 we've been here for 9 hours. I had not been told</p> <p>2 that that was going to happen today. I actually</p> <p>3 have a prior commitment that I really need to go</p> <p>4 to, and I believe the doctor is tired as well.</p> <p>5 So I've agreed, and I think you have,</p> <p>6 too, that we would go ahead and allow you that</p> <p>7 time for the warnings opinions that you have and</p> <p>8 set it up at an additional time.</p> <p>9 MR. SNELL: And at a mutually</p> <p>10 convenient date between doctor, myself, and</p> <p>11 whoever will defend.</p> <p>12 MR. CARTMELL: That's right.</p> <p>13 MR. SNELL: And I will just state for</p> <p>14 the record, too, Ben Anderson never told me he</p> <p>15 expected me to do both in 7 hours, nor does he</p> <p>16 have a basis under the New Jersey Rules of</p> <p>17 Procedure to make such a statement. I have my</p> <p>18 email that I sent to him, and there was no reply</p> <p>19 saying, no, Burt, you're wrong.</p> <p>20 MR. CARTMELL: Okay.</p> <p>21 MR. SNELL: But we have an agreement,</p> <p>22 and I'm passing the witness. Let's get this</p> <p>23 design defect deposition in the books.</p> <p>24 MR. CARTMELL: Okay.</p> <p>25 MR. SNELL: That way you can go do</p>	<p>1 A. That based upon the medical</p> <p>2 literature, Klosterhalfen, Klinge, as stated in my</p> <p>3 report, lightweight large pore meshes have lower</p> <p>4 complication rates, and that is also including the</p> <p>5 internal Ethicon documents that state</p> <p>6 acknowledgment of that fact.</p> <p>7 Q. You mentioned, when you were</p> <p>8 questioned by Mr. Snell, that the TVT, I believe</p> <p>9 you said during the first six weeks, may result in</p> <p>10 more pain.</p> <p>11 Do you recall that?</p> <p>12 MR. SNELL: Objection. Misstates.</p> <p>13 A. I don't believe I said that. That the</p> <p>14 TVT may result in more pain? No, I didn't --</p> <p>15 Q BY MR. CARTMELL: You didn't say that?</p> <p>16 A. I didn't say that.</p> <p>17 Q. I think you were talking about</p> <p>18 perioperative pain when comparing the TVT to maybe</p> <p>19 pubovaginal slings or the Burch.</p> <p>20 A. Correct.</p> <p>21 Q. Okay. When you were talking about</p> <p>22 pain during that perioperative period or during</p> <p>23 the first six weeks, what type of pain were you</p> <p>24 talking about?</p> <p>25 A. I'm talking about incisional pain,</p>
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<p>1 your thing.</p> <p>2 MR. CARTMELL: Doctor, I just have a</p> <p>3 few follow-up questions.</p> <p>4 You recall that you were asked</p> <p>5 previously about --</p> <p>6 MR. SNELL: Can you give me one</p> <p>7 second, Tom. I'm essentially sorry to interrupt</p> <p>8 you. I just have to get something to write with.</p> <p>9 Very, very sorry. Go ahead. I'll shut up.</p> <p>10 EXAMINATION</p> <p>11 BY MR. CARTMELL:</p> <p>12 Q. Do you recall being asked questions by</p> <p>13 Mr. Snell about large pore lightweight mesh?</p> <p>14 A. Yes.</p> <p>15 Q. And do you have an opinion within a</p> <p>16 reasonable degree of medical certainty that</p> <p>17 lightweight large pore mesh would lead to less</p> <p>18 complications in the TVT or in a mid-urethral</p> <p>19 sling than the TVT heavy weight small pore mesh?</p> <p>20 A. Yes.</p> <p>21 MR. SNELL: Objection. Leading. Go</p> <p>22 ahead.</p> <p>23 A. Yes.</p> <p>24 Q BY MR. CARTMELL: And what is your</p> <p>25 opinion?</p>	<p>1 pain in the suprapubic region, where the tissue</p> <p>2 may have been harvested. I'm not talking about</p> <p>3 vaginal discomfort. That would be equal. We're</p> <p>4 just giving the harvest area.</p> <p>5 Q. Are you talking about dyspareunia?</p> <p>6 A. No. I'm talking specifically</p> <p>7 perioperative incisional pain.</p> <p>8 Q. Do you have an opinion within a</p> <p>9 reasonable degree of medical certainty whether or</p> <p>10 not TVT, when compared to pubovaginal slings or</p> <p>11 Burch slings, causes more dyspareunia or vaginal</p> <p>12 pain on a long-term basis?</p> <p>13 MR. SNELL: Objection. Beyond the</p> <p>14 scope. Non-disclosed opinion in the report.</p> <p>15 Go ahead.</p> <p>16 A. Based upon my clinical experience, my</p> <p>17 discussion with colleagues, review of the</p> <p>18 literature, and what is outlined in my expert</p> <p>19 report, TVT, in the long-term, causes increased</p> <p>20 risk for dyspareunia and the severity of that</p> <p>21 dyspareunia.</p> <p>22 Q BY MR. CARTMELL: What about with</p> <p>23 vaginal pain?</p> <p>24 A. Vaginal pain would be the --</p> <p>25 MR. SNELL: Same objection. Go ahead.</p>

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<p>1 Doctor. I'm sorry.</p> <p>2 A. They would be the same. Vaginal pain</p> <p>3 implies a constant vaginal pain. Dyspareunia is</p> <p>4 just during sexual activity. And, yes, in my</p> <p>5 experience, I do not see pubovaginals and Burchs</p> <p>6 come in with that type of pain. On a daily basis,</p> <p>7 I see the TVT that way.</p> <p>8 MR. CARTMELL: Okay. That's all I</p> <p>9 have.</p> <p>10 MR. SNELL: A couple of quick</p> <p>11 questions in follow-up.</p> <p>12 EXAMINATION</p> <p>13 BY MR. SNELL:</p> <p>14 Q. Cobb, Klosterhalfen and Klinge, none</p> <p>15 of those are pelvic surgeons; correct?</p> <p>16 A. Clave, I don't know what he is. The</p> <p>17 first two, Klinge and Klosterhalfen are</p> <p>18 pathologists, I believe.</p> <p>19 Q. Cobb is not --</p> <p>20 A. Cobb is not. And I don't know if I</p> <p>21 mentioned it. I mentioned -- Clave should be on</p> <p>22 there, and I believe he is a pelvic surgeon, but I</p> <p>23 don't know his specific credentials.</p> <p>24 Q. But Cobb, Klosterhalfen, Klinge, none</p> <p>25 of them published on the TVT device assessed in</p>	<p>1 pain from either of those aforementioned</p> <p>2 procedures. But I see it commonly, weekly with</p> <p>3 the meshes, including the TVT.</p> <p>4 Q. You can't point to any comparative</p> <p>5 trials that show a statistically significantly</p> <p>6 higher rate of dyspareunia for the TVT retropubic</p> <p>7 device compared to either the Burch or the</p> <p>8 pubovaginal sling; correct?</p> <p>9 A. Those studies, as you've mentioned,</p> <p>10 have not been done.</p> <p>11 Q. And actually, the one paper you</p> <p>12 pointed me to earlier about the Burch had the</p> <p>13 4 percent rate of dyspareunia with that procedure</p> <p>14 long-term; correct?</p> <p>15 A. It wasn't 4 percent. It was</p> <p>16 3.9 percent.</p> <p>17 Q. So -- okay. If you round up, it's</p> <p>18 4 percent; correct?</p> <p>19 A. I don't round up, though.</p> <p>20 Q. Okay. And you can't point to any</p> <p>21 studies on TVT that show a rate higher than</p> <p>22 3.9 percent at that length of follow-up for</p> <p>23 dyspareunia; can you?</p> <p>24 MR. CARTMELL: Object to the form.</p> <p>25 A. Because that study has not been done.</p>
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<p>1 women; correct?</p> <p>2 A. That is correct, yes.</p> <p>3 Q. Just so we're clear on the record, the</p> <p>4 increased perioperative incisional pain that you</p> <p>5 just talked to Mr. Cartmell about, that actually</p> <p>6 occurs in the autologous pubovaginal arm; is that</p> <p>7 correct?</p> <p>8 A. That is correct. It would be fair to</p> <p>9 say that, in my experience, the immediate</p> <p>10 perioperative period, you will have an increased</p> <p>11 incisional pain that is still treated with</p> <p>12 medications and tolerable, but it will be more</p> <p>13 than the TVT.</p> <p>14 Q. Now, I believe you said that you</p> <p>15 believe that the long-term dyspareunia rates with</p> <p>16 the TVT were higher than pubovaginal, did you say,</p> <p>17 and the Burch?</p> <p>18 A. I don't recall if I mentioned the</p> <p>19 Burch in there.</p> <p>20 What I mentioned was the pubovaginal</p> <p>21 and the Burch have traditionally been a very</p> <p>22 common procedure done up until the mid-'90s and</p> <p>23 into probably early 2000's.</p> <p>24 And in my practice, I have never seen</p> <p>25 a woman come in with severe pain, life altering</p>	<p>1 As I mentioned, no studies focused specifically on</p> <p>2 output -- end point of dyspareunia have been done.</p> <p>3 Q BY MR. CARTMELL: So the answer to my</p> <p>4 question is, yes, you can't point to that study;</p> <p>5 correct?</p> <p>6 MR. CARTMELL: Object to the form.</p> <p>7 Asked and answered.</p> <p>8 A. That's what I mentioned. Those</p> <p>9 studies with that specific end point have not been</p> <p>10 done.</p> <p>11 Q BY MR. CARTMELL: Except you know that</p> <p>12 there's a 10-year TVT retropubic study, lead</p> <p>13 author Heinonen, that reports zero cases of</p> <p>14 dyspareunia at 10 years follow-up.</p> <p>15 Did you know that?</p> <p>16 A. You would have to show me that study.</p> <p>17 Q. Do you know that study?</p> <p>18 A. I'm saying, you'd have to show me that</p> <p>19 study. I've read a lot of studies. I can't</p> <p>20 recall that one specifically. So I'd have to look</p> <p>21 at that.</p> <p>22 Q. So you very well may be wrong when you</p> <p>23 make statements like there's no long-term studies</p> <p>24 that look at TVT and dyspareunia?</p> <p>25 MR. CARTMELL: Object to the form.</p>

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<p style="text-align: right;">Page 330</p> <p>1 Q. BY MR. SNELL: Correct?</p> <p>2 A. Also certain studies I've looked at, I</p> <p>3 disregard --</p> <p>4 Q. Can you say yes or no?</p> <p>5 MR. CARTMELL: Let him answer the</p> <p>6 question?</p> <p>7 A. That's not a yes or no. It's more</p> <p>8 complicated than that. I review a lot of studies.</p> <p>9 Some of them get disregarded because they're so</p> <p>10 poor quality that they're not worth quoting. So</p> <p>11 that particular study I'd like to see and we can</p> <p>12 dissect that one out.</p> <p>13 Q. And if I'm correct --</p> <p>14 MR. CARTMELL: You said a couple. So</p> <p>15 you went over 7 hours. And I'm here for the MDL</p> <p>16 portion.</p> <p>17 MR. SNELL: I didn't go over 7 hours.</p> <p>18 MR. CARTMELL: You went 7 hours and 13</p> <p>19 minutes.</p> <p>20 MR. SNELL: No, no. That was 6 hours;</p> <p>21 wasn't it?</p> <p>22 MR. CARTMELL: No. It was 7 hours and</p> <p>23 13 minutes. I let you ask a few. We done.</p> <p>24 MR. SNELL: Okay.</p> <p>25 MR. CARTMELL: And you could have</p>	<p style="text-align: right;">Page 332</p> <p>1 compared to the mid-urethral sling; correct?</p> <p>2 A. I'd have to look at that. That's a</p> <p>3 799-page document. I'd have to see that.</p> <p>4 Q. As you sit here today, you can't</p> <p>5 answer my question?</p> <p>6 A. Oh, I can answer. Let's pull out the</p> <p>7 document, take a look at it.</p> <p>8 Q BY MR. SNELL: Do you want to do that?</p> <p>9 MR. CARTMELL: I mean, I'm not giving</p> <p>10 you any more time. So you don't have the time to</p> <p>11 do that. This whole day you've been asking him</p> <p>12 questions about things and you've been making</p> <p>13 statements from those documents without showing</p> <p>14 them to him.</p> <p>15 MR. SNELL: No, no. He's got these</p> <p>16 documents.</p> <p>17 MR. CARTMELL: No, no.</p> <p>18 MR. SNELL: I wouldn't misrepresent.</p> <p>19 MR. CARTMELL: All day long.</p> <p>20 MR. SNELL: Do you want me to show him</p> <p>21 the numbers? You know the numbers. I used them</p> <p>22 with Dr. Rosenswath.</p> <p>23 MR. CARTMELL: No. I want to be done.</p> <p>24 You're over your 7 hours. So let's go.</p> <p>25 Q BY MR. SNELL: As you sit here,</p>
<p style="text-align: right;">Page 331</p> <p>1 saved your time.</p> <p>2 MR. SNELL: Well, I have two more</p> <p>3 considering you've asked him to comment and say</p> <p>4 rates are higher. That's not even in his expert</p> <p>5 report, okay. He doesn't put in his expert report</p> <p>6 what the rates are for Burch, for the pubovaginal,</p> <p>7 or the TVT.</p> <p>8 MR. CARTMELL: I didn't ask him what</p> <p>9 the rates were.</p> <p>10 MR. SNELL: Yes, you did.</p> <p>11 MR. CARTMELL: No, I didn't. I</p> <p>12 said --</p> <p>13 MR. SNELL: You said higher.</p> <p>14 MR. CARTMELL: -- the claim is it's</p> <p>15 higher, and it says that in his expert report.</p> <p>16 MR. SNELL: No, it doesn't.</p> <p>17 MR. CARTMELL: Yes, it does.</p> <p>18 MR. SNELL: It can't be higher. He</p> <p>19 doesn't even have the rates.</p> <p>20 Q BY MR. SNELL: How about this? You've</p> <p>21 seen the AUA guideline from 2012 and the SGS</p> <p>22 systematic meta-analysis and review, and in both</p> <p>23 of those systematic reviews, they report higher</p> <p>24 rates of dyspareunia, pain, and sexual dysfunction</p> <p>25 with the autologous sling and the Burch as</p>	<p style="text-align: right;">Page 333</p> <p>1 Doctor, can you answer my question without me</p> <p>2 showing you those papers?</p> <p>3 A. I want to see those papers.</p> <p>4 MR. CARTMELL: No.</p> <p>5 MR. SNELL: Fair enough.</p> <p>6 MR. CARTMELL: The question was: Can</p> <p>7 you answer it without seeing the papers. If you</p> <p>8 can't answer it without seeing it, just say no.</p> <p>9 A. I cannot answer it without it. It's a</p> <p>10 799-page document. I would need to see those</p> <p>11 papers.</p> <p>12 MR. SNELL: Fair enough.</p> <p>13 MR. CARTMELL: Go ahead. Thank you</p> <p>14 very much.</p> <p>15 (Deposition concluded at 5:54 p.m.)</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<p>1 REPORTER'S CERTIFICATE</p> <p>2</p> <p>3 I, NAOLA C. VAUGHN, a Certified Court</p> <p>4 Reporter within and for the States of Missouri and</p> <p>5 Kansas, hereby certify that the within-named witness</p> <p>6 was first duly sworn by me to testify to the truth;</p> <p>7 and that the deposition by said witness was given in</p> <p>8 response to the questions propounded, as herein set</p> <p>9 forth; was first taken in machine shorthand by me</p> <p>10 and afterwards reduced to writing under my direction</p> <p>11 and supervision; and is a true and correct record of</p> <p>12 the testimony given by the witness.</p> <p>13 I further certify that I am not a relative</p> <p>14 or employee or attorney or counsel of any of the</p> <p>15 parties, or a relative or employee of such attorneys</p> <p>16 or counsel, or financially interested in the action.</p> <p>17 WITNESS my hand and official seal at</p> <p>18 Tonganoxie, Kansas, this 29th day of September 2015.</p> <p>19</p> <p>20</p> <p>21</p> <p>22 NAOLA C. VAUGHN, CCR, CRR, RPR</p> <p>23 Missouri CCR No. 1052</p> <p>24 Kansas CCR No. 0895</p> <p>25</p>	<p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 REASON: _____</p> <p>6 _____</p> <p>7 REASON: _____</p> <p>8 _____</p> <p>9 REASON: _____</p> <p>10 _____</p> <p>11 REASON: _____</p> <p>12 _____</p> <p>13 REASON: _____</p> <p>14 _____</p> <p>15 REASON: _____</p> <p>16 _____</p> <p>17 REASON: _____</p> <p>18 _____</p> <p>19 REASON: _____</p> <p>20 _____</p> <p>21 REASON: _____</p> <p>22 _____</p> <p>23 REASON: _____</p> <p>24 _____</p> <p>25 REASON: _____</p>
<p>Page 335</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it. It will be</p> <p>10 attached to your deposition.</p> <p>11 It is imperative that you</p> <p>12 return the original errata sheet to the</p> <p>13 deposing attorney within thirty (30) days</p> <p>14 of receipt of the deposition transcript</p> <p>15 by you. If you fail to do so, the</p> <p>16 deposition transcript may be deemed to be</p> <p>17 accurate and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3 I, _____, do</p> <p>4 hereby certify that I have read the</p> <p>5 foregoing pages, and that the same</p> <p>6 is a correct transcription of the answers</p> <p>7 given by me to the questions therein</p> <p>8 propounded, except for the corrections or</p> <p>9 changes in form or substance, if any,</p> <p>10 noted in the attached Errata Sheet.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15 DANIEL STEVEN ELLIOTT, M.D. DATE</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p>Subscribed and sworn</p> <p>to before me this</p> <p>_____ day of _____, 20____.</p> <p>My commission expires: _____</p> <p>Notary Public</p>

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## Original Article: Clinical Investigation

# Tension-free vaginal tape procedure without preoperative urodynamic examination: Long-term outcome

Pia Heinonen,<sup>1</sup> Seija Ala-Nissilä,<sup>2</sup> Pentti Kiilholma<sup>1</sup> and Eija Laurikainen<sup>2</sup>

<sup>1</sup>Turku University, and <sup>2</sup>Department of Obstetrics and Gynecology, Turku University Hospital, Turku, Finland

### Abbreviations & Acronyms

BMI = body mass index  
 DIS = Detrusor Instability Score  
 EQ-5D VAS = European quality of life – visual analog scale  
 EuroQoL-5D = European quality of life-five dimensions  
 IIQ-7 = Incontinence Impact Questionnaire-7  
 ISD = intrinsic sphincteric deficiency  
 MUI = mixed urinary incontinence  
 NS = not significant  
 SD = standard deviation  
 SUI = stress urinary incontinence  
 TOT = transobturator tape  
 TVT = tension-free vaginal tape  
 UDI-6 = Urogenital Distress Inventory-6  
 UISS = Urinary Incontinence Severity Score  
 UUI = urgency urinary incontinence  
 VAS = visual analog scale

**Objectives:** To evaluate the long-term outcome of the tension-free vaginal tape procedure.

**Methods:** A total of 191 patients were operated on with tension-free vaginal tape between January 1998 and May 2000. Of these, 127 (66%) had stress urinary incontinence, 64 (34%) had mixed urinary incontinence and 39 (20%) had recurrent incontinence. A total of 34 (18%) patients had had concomitant surgery. The diagnosis of incontinence was based on a history of leakage during stress and physical examination with a supine stress test in all patients. Tension-free vaginal tape was carried out under local (82%) or spinal (18%) anesthesia. After a mean of 10.5 years follow up, the assessment included a gynecological examination and a supine stress test. Subjective outcome was evaluated with Urinary Incontinence Severity Score, Detrusor Instability Score, visual analog scale, European quality of life-five dimensions, European quality of life – visual analog scale and short versions of Incontinence Impact Questionnaire-7 and Urogenital Distress Inventory-6. Objective cure was defined as a negative stress test and an absence of reoperation for incontinence during the follow up.

**Results:** A total of 138 (72%) of 191 patients were evaluated. Patients with minimally invasive surgery before operation had significantly higher scores in Urinary Incontinence Severity Score, Detrusor Instability Score, Incontinence Impact Questionnaire-7 and Urogenital Distress Inventory-6 at follow up than the patients with stress urinary incontinence ( $P < 0.01$ ). Recurrent incontinence and concomitant surgery did not affect the long-term outcome. Three patients (2.3%) had late-onset adverse events. The objective and subjective cure rates were 90% and 78%, respectively.

**Conclusions:** The tension-free vaginal tape procedure is effective and safe even after 10 years. The objective cure rate is high, but the subjective outcome is significantly lower in mixed urinary incontinence patients compared with patients with pure stress urinary incontinence. Recurrent stress urinary incontinence does not affect the outcome, and tape-related problems are rare.

**Key words:** follow-up studies, minimally invasive surgery, stress urinary incontinence, suburethral slings, tension-free vaginal tape.

**Correspondence:** Pia Heinonen M.D., Department of Obstetrics and Gynecology, University of Turku, Turku 20520, Finland. Email: pia.heinonen@tyks.fi

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## Introduction

The overall prevalence of female SUI among females over the age of 18 years is approximately 30%,<sup>1</sup> but is increasing with age.<sup>2</sup> SUI can be treated surgically, and minimally invasive techniques have been developed to minimize surgical complications, and to improve outcome and patient satisfaction. The TVT technique was introduced by Ulmsten in 1996, and has become the gold standard for treating female SUI.<sup>3</sup> In TVT, a tape is placed loosely under the midurethra through the retropubic space. According to the few long-term follow-up studies that are available, cure rates have been satisfying for TVT and mesh-related adverse events are rare.<sup>4,5</sup>

The aim of the present study was to report the effectiveness, subjective and objective outcomes, and late adverse events among patients who underwent TVT a mean of 10.5 years

ago without preoperative urodynamic examination. The short-term outcome of the present study population has already been published.<sup>6</sup>

## Methods

The present study is a follow-up study of 191 patients operated on with the TVT procedure between January 1998 and May 2000 at the Department of Obstetrics and Gynecology in the Turku City Hospital, Turku, Finland. The Departments of Obstetrics and Gynecology of the Turku City Hospital and of the University Hospital were joined in 2004, and therefore this follow up was not carried out in the same hospital as the original operation. All the operations were carried out by senior gynecologists. Most (90%) of the procedures were carried out by one surgeon (PK). The study population has been presented previously.<sup>6</sup> A total of 127 patients (66%) had SUI and 64 (34%) had MUI with SUI symptoms dominating. In the original cohort, 39 (20%) patients had recurrent incontinence with previous anti-incontinence operations, which were colposuspension in 23 cases (19 open and 4 laparoscopic), vaginal incontinence operation in 12 (including one TVT) and periurethral injection in six patients. Furthermore, one patient had undergone bladder neck discision because of retention and overflow incontinence.

The diagnosis of incontinence was based on a history of leakage during stress and physical examination with a supine stress test in all patients. In over half of the cases the UISS<sup>7</sup> (Appendix 1), the DIS<sup>7,8</sup> (Appendix 2) was also filled in. Urogynecological perineal ultrasonography was carried out to examine the patients who had a history of MUI in order to verify the SUI component.<sup>9</sup> Also, of the 39 patients with recurrent incontinence, 22 patients underwent preoperative ultrasonography. In the original study population, all patients were primarily treated with pelvic floor exercise including instructions for bladder training and secondarily with anti-cholinergic medication if required.<sup>6</sup>

Vaginal, systemic or combined hormone replacement therapy was used by 119 (62%) patients. The procedure was carried out as previously described<sup>3</sup> under local (82%) or spinal (18%) anesthesia with perioperative cystoscopy. The tape (TVT Gynecare; Ethicon, Somerville, NJ, USA) was loosely placed under the midurethra. An intraoperative stress test with 300 mL bladder filling was used to adjust the tape in all patients regardless of the method of anesthesia. One dose of 500 mg metronidazole was given intravenously for antibiotic prophylaxis immediately before the operation. Concomitant surgery was carried out in 34 (18%) patients; 13 procedures were carried out for pelvic organ prolapse and 21 vaginal hysterectomies were carried out because of heavy bleeding or uterine fibroids.

After a mean of 10.5 years (range 9–12 years), postal questionnaires were sent to all patients together with an

invitation for a charge-free follow-up visit at the Turku University Hospital, Outpatient Clinic of Gynecology. A reminder was sent to those who did not respond to the first questionnaire. Attempts were made to contact non-respondents by telephone. They were asked about symptoms of SUI, urgency or UII and any late adverse events, as well as satisfaction with the operation.

Subjective outcome was evaluated with condition-specific questionnaires: the UISS, the DIS, short versions of the IIQ-7 and the UDI-6, and a VAS 0–100.<sup>10</sup> UISS and DIS have been designed by the urogynecological working groups of Finnish and Nordic Gynecological Societies. UISS demonstrates symptom severity and the impact of urinary incontinence on everyday life, and DIS symptoms of detrusor instability and its degree. These questionnaires are widely used in Finland, as in other Scandinavian countries.<sup>7,8</sup> In the DIS questionnaire, scores  $\leq 7$  refer to pure SUI and the more scores that are calculated, the more symptoms of urgency exists.<sup>8</sup> The patients' general quality of life and health was assessed with EQ-5D and EQ-5D VAS. If a patient left more than two items unanswered in the IIQ-7 or UDI-6 questionnaires, a total score was not calculated. The patient was considered to be satisfied with the procedure if the total score of the IIQ-7 questionnaire was 0–7<sup>11</sup> and if they expressed satisfaction at the telephone interview. If the score in the DIS questionnaire was more than 7, and if the patient had moderate or severe frequency or urgency (scores 2 or 3) in questions one and two of the UDI-6 questionnaire, the patient was considered to have urgency or UII.

At the follow-up visit, a gynecological examination and a supine stress test with a 250–300 mL bladder volume were carried out. The hospital records of all the patients were reviewed to examine whether the patients had had visits to the hospitals in the Hospital District of Southwest Finland. This was done to acquire information on later acquired systemic diseases, gynecological or anti-incontinence operations, urinary symptoms and adverse events after the TVT-operation.

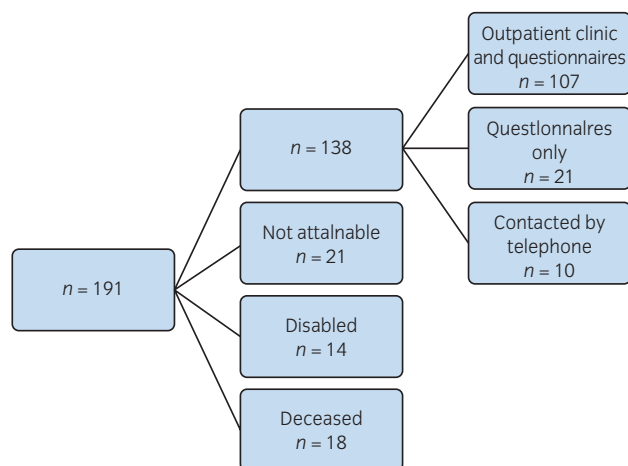
Objective cure was defined as a negative stress test and no need for a reoperation for SUI.

The SAS system for Windows version 9.2 (SAS Institute, Cary, NC, USA) was used for tabulations and statistical analysis.

The study was approved by the Ethics Committee of the Hospital District of Southwest Finland.

## Results

A total of 138 (72%) out of 191 patients were evaluated at a mean of 10.5 years postoperatively (Fig. 1). Of these, 127 (66% of the original cohort) both answered the questionnaires and visited the outpatient clinic. A total of 21 (11%) patients were unwilling to attend the follow-up visit and only returned the questionnaires. A total of 18 (9% of the



**Fig. 1** Study population.

original cohort) patients had died during the follow up of unrelated causes. Of the 35 (21%) patients who did not participate in the evaluation, 21 (11%) were not reached and 14 (7%) were too disabled to attend, mainly because of cognitive disorders. Ten patients could be contacted by telephone.

The mean follow-up time was 126.5 months (range 108–145 months). The mean age at the follow up was 69 years (range 48–93 years). The patient characteristics are presented in Table 1.

Out of 64 patients with MUI preoperatively, 58% (37 patients) and 80% (101 patients out of 127) of SUI patients participated in the present study. By the time of the surgery, the mean age for MUI patients who didn't participate in the present follow-up study was 67 years, whereas the mean age for the whole study group was 60 years.

Of the 128 patients, 100 (78%) had a score of 0–7 in IIQ-7, which is considered as a satisfactory subjective outcome.<sup>11</sup> The results of the questionnaires are presented in Table 2. In all condition-specific questionnaires (UISS, DIS, UDI-6, IIQ-7), all the results were significantly poorer in patients with MUI compared with those with SUI (Table 2). Also, in questionnaires assessing patients' general quality of life and health (EQ-5D and EQ-5D VAS), MUI patients had significantly poorer results. Five patients did not reply to more than two questions in the IIQ-7 or UDI-6 questionnaires, and therefore a total score was not calculated for these patients. Ten out of 37 MUI patients (27%) had persistent urgency at the time of follow up. Six (6.6%) patients developed de novo urgency. The occurrence of urgency was of similar frequency among patients aged over 7 years as among younger patients (34% vs 47%,  $P = 0.18$ ).<sup>12</sup>

A total of 18 (14%) patients had a DIS score >7, and at the same time moderate or severe scores at the first and the second questions of the UDI-6 questionnaire indicating urgency or UUI. Patients with chronic illnesses had a poorer health-related quality of life, as assessed with EQ-5D VAS

**Table 1** Characteristics of the patients in the original cohort operated on using TVT and in patients evaluated objectively or with the questionnaires after a mean of 10.5 years postoperatively

	Original cohort (n = 191)	Evaluated cohort (n = 128)†
Median age (years)	60	68
Median BMI	27	26
Estrogen (n)‡	119	77
Chronic illnesses (n)§	74 (39%)	100 (78%)
• Diabetes	3	10
• Cardiovascular	61	68
• Neurological	4	7
• Respiratory	14	9
Previous gynecological surgery (n)	110	
• Incontinence surgery	39	
• Hysterectomy	77	
• Vaginal prolapse surgery	24	
Surgery after the TVT operation (n)		
• Incontinence surgery		6
• Bulking agent¶		1
• Hysterectomy		5
• Vaginal prolapse surgery		4

†The 10 patients contacted by telephone are not included in this cohort. ‡Vaginal and/or systemic estrogen. §One patient might have had one or more chronic illnesses. ¶Polyacrylamide hydrogel.

and EQ-5D than healthy patients (65 vs 74 and 8.1 vs 9.3, respectively,  $P < 0.05$  for both). In regard to the patients with recurrent SUI, 12 (31%) out of 39 patients were diagnosed to have MUI preoperatively. There were no statistically significant differences in the results of the questionnaires compared with patients with primary SUI and those with recurrent SUI (Table 3). Of the 10 patients who were contacted by telephone, seven were continent and satisfied with the operation, whereas two of the patients had MUI and one UUI.

Among the 107 patients who were eligible for objective evaluation, a stress test was negative for 100 (93%) patients. The TVT procedure was considered a failure in 11 (10%) patients: six patients had undergone a repeat anti-incontinence procedure and a stress test was positive in six patients, including one reoperated patient with a positive stress test. Repeat anti-incontinence procedures were TVT in one patient and TOT in five patients. One patient of the latter group has had two transobturator procedures; with outside-in and inside-out technique. All these patients are now stress continent, though two of them are using anticholinergic medication for urgency symptoms. These reoperated patients were not included in the analysis. The mean

**Table 2** Results of the questionnaires at the time of follow up a mean of 10.5 years after the TVT operation

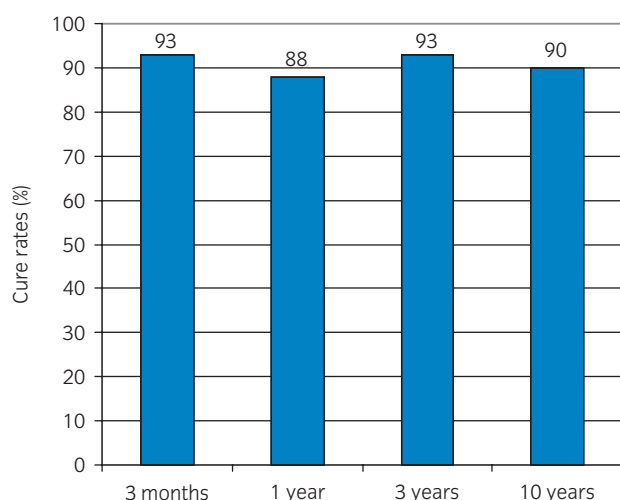
<i>n</i> = 128	SUI† mean ± SD	Range	MUI† mean ± SD	Range	<i>P</i> -value‡
IIQ-7 (0–21)	1.8 ± 3.5	0–21	5.7 ± 5.9	0–21	<0.001
UDI-6 (0–18)	3.6 ± 2.9	0–13	7.1 ± 4.9	0–17	<0.001
EQ-5D VAS (0–100)	73 ± 21	10–100	63 ± 19.5	15–100	<0.05
EQ-5D (6–18)	8.3 ± 1.8	6–14	9.1 ± 2.1	6–16	<0.05
VAS (0–100)	22 ± 25.4	0–90	42.7 ± 34	0–100	<0.001
UISS (0–100)	12.9 ± 16.6	0–78	33 ± 25.4	0–90	<0.001
DIS (0–20)	5.3 ± 3.1	0–11	8.9 ± 4.2	0–16	<0.001

†SUI or MUI before the TVT operation. ‡*P*-value representing differences in scores in SUI and MUI patients.

**Table 3** Results of the questionnaires evaluating subjective outcome in patients with primary and recurrent SUI after the 10.5 years follow-up

	Primary SUI mean ± SD	Range	Recurrent SUI mean ± SD	Range	<i>P</i> -value
IIQ-7 (0–21)	9.9 ± 5	0–28	9.3 ± 3.5	7–20	NS
UDI-6 (0–18)	10.6 ± 4.2	0–23	9.8 ± 3.2	6–19	NS
EQ-5D VAS (0–100)	71.4 ± 19.6	10–100	65.2 ± 65.2	15–100	NS
EQ-5D (6–18)	8.4 ± 1.9	6–16	9.2 ± 2.0	7–14	NS
VAS (0–100)	27.6 ± 29.5	0–95	28.4 ± 28.4	0–100	NS
UISS (0–100)	19.7 ± 22.2	0–90	16.3 ± 19.5	0–70	NS
DIS (0–20)	6.3 ± 3.9	0–16	6.8 ± 3.4	0–13	NS

NS indicates *P*-value >0.05.



**Fig. 2** Objective cure rates after the TVT operation at 3 months, 1 year, 3 years and 10 years follow up. Objective cure rates after 3 months, 1 year and 3 years. Reproduced from Laurikainen *et al.*,<sup>6</sup> with permission. ■, %.

age of the six patients with a positive stress test was 79 years. Two of these patients were primarily operated on because of recurrent SUI. The objective cure rate for the patients with MUI before TVT was 93% (37/40 patients)

and with SUI it was 94% (63/67). The overall objective cure rate was 90% of the 107 evaluated patients. The results and cure rates at earlier time-points have been presented in a previous publication (Fig. 2).<sup>6</sup>

In this evaluated cohort, local anesthesia was used in 88% of the patients and spinal anesthesia in 12%. The type of anesthesia did not affect the outcome, nor did any concomitant surgical procedures affect the scores.

The TVT tape was cut below the urethra in two patients; one because of urinary retention at 1 year after the operation and another because of pain at 8 years. The symptoms of both patients disappeared after the re-intervention and the patients remained stress continent. The patient with urinary retention also had urgency incontinence, which was successfully treated with anticholinergic medication and pelvic floor physiotherapy. Recurrent urinary tract infections and pain during urination appeared in one patient 9 years after the TVT procedure. A fibero cystoscopy was carried out by a urologist and a small part of calcificated tape was found to be eroded into the bladder on the right side of the bladder neck. A visible part of the tape was resected at repeat cystoscopies three times. At the latest control more than 11 years after the operation, the patient still had recurrent urinary tract infections and difficulties in emptying the bladder. An abdominal computed tomography and cystos-

copy was scheduled to locate the exact position of the tape. The original TVT operation was carried out uneventfully. A cystoscopy was carried out twice after the insertion of the tape at both sides routinely, as advised in the original TVT technique during the primary operation,<sup>3</sup> and no abnormal findings; for example, perforation or folding of the bladder wall, were discovered. Hospital records of the original cohort did not show any additional complications.

## Discussion

The TVT-procedure has become the gold standard of female incontinence surgery. Short-term efficacy and safety have been well demonstrated in numerous studies,<sup>13,14</sup> but there is a paucity of long-term data. In two studies with follow up more than 10 years, objective cure rates were 90% and 84%, respectively.<sup>4,5</sup> Accordingly, in the present study, objective cure of SUI was found to be 90% and subjective cure 78%. The TVT operation is a highly standardized procedure with a routine performance including an intraoperative stress test under local anesthesia, and a cystoscopy after insertion of the tape at each side.<sup>3</sup> When TVT was introduced in Finland, systematic, nationwide, hands-on training for gynecological surgeons was executed.<sup>15</sup> This might contribute to the relatively high cure rates after the long-term follow up.

In the present follow-up study, the outcome could be evaluated objectively in 107 patients and subjectively in 138 patients of the 191 patients who had undergone the TVT procedure a mean of 10.5 years ago. A total of 18 patients had died, and 14 were unable to attend a charge-free follow-up visit to an outpatient clinic. Some patients could not be reached by postal invitation, and some declined participation, partially as they were initially operated on in a hospital different from the follow-up site. The readiness to participate the present study might also have been affected by the relatively high median age of the patients, 68 years. The oldest participant was 93 years. However, the risk of non-responder bias has to be taken into account when interpreting the results of the present study.

There are some studies showing that TVT is also an effective way to treat patients with MUI.<sup>13,16</sup> In contrast, in the present study population,<sup>6</sup> the short-term cure rate of the patients with MUI was significantly lower than of the SUI patients at 36 months of follow up, 69% versus 97%. The same tendency also persisted in the long-term follow up. However, just 58% of the MUI patients participated the present study. The mean age of MUI patients was 7 years higher than that of the SUI patients, which might have affected the readiness of MUI patients to attend. Subjective outcome is likely to be poorer with MUI patients, because of persistent urgency or UII symptoms. It is obvious, that the stress test is not ideal for testing urgency incontinence symptoms objectively. Omitting preoperative urodynamic testing might be associated with poorer subjective results in

MUI patients. The risk of an unsatisfying result is higher with a patient with MUI and should be taken into consideration in connection with the preoperative counselling, as urgency before the operation is predictive of patient satisfaction.<sup>17</sup>

Three years after TVT, the present patient population had a 60% improvement in their urgency symptoms, whereas 4.8% of the patients presented de novo urgency symptoms. After a mean of 10.5 years, de novo urgency was reported by six (6.6%) patients. Previously, de novo urgency or UII has been reported in 1.5–22% patients after TVT during a follow up from 12 to 36 months.<sup>13,18</sup> De novo urgency is regarded as the most common long-term adverse event after surgical treatment of female SUI. Indeed, it might be even more troublesome for the patient than preoperative SUI.<sup>19</sup> In contrast, after the TVT, urgency symptoms will abate in 54–93% of patients.<sup>5,13</sup> Increasing urgency rates during the follow up might preferentially relate to aging, as the incidence and severity of symptoms of overactive bladder increase progressively with age.<sup>20,21</sup>

The TVT procedure is effective for the treatment of recurrent SUI when the follow-up time has been 20–60 months.<sup>22–24</sup> Rezapour and Ulmsten reported an 82% cure rate and 8% significant improvement of stress urinary incontinence in the study population where some patients have had several operations before the TVT.<sup>25</sup> As repeat surgical intervention, medium cure rates after TOT seem to be lower than after TVT in women with ISD.<sup>22,26</sup> The low pressure urethra and impaired urethral mobility are the risk factors predictive of failure of repeat incontinence surgery.<sup>22,27</sup> Urodynamic examination is required to identify patients with ISD and to guide the surgeon to choose the TVT procedure in these cases. Previous operations might impair urethral function and increase the risk of complications as a result of scarring and altered anatomy. Thus, it is not surprising that the incidence of urgency and UII are more common after recurrent operations than after the first operation. In the present study, patients operated on with TVT as a repeat procedure had the same long-term outcome than patients with primary SUI.

In the present study, three patients suffered from late tape-related adverse events at 1–11 years postoperatively. In all these cases, the initial TVT procedure and immediate recovery after that proceeded as expected. Two patients with retention and pain had the tape cut without any further problems. One patient had recurrent urinary tract infections and dysuria as a result of tape erosion into the bladder and had to undergo at least three cystoscopies to remove the visible tape from the bladder wall. Irritating symptoms, recurrent urinary tract infections and pain during urination might emerge several years after the primary operation, and need to be taken into consideration as a sign of late complication of TVT. Tape erosion might develop because of possible submucosal placement of the tape or pressure necrosis



of the bladder wall.<sup>28,29</sup> In patients with prolonged or later-appearing urinary symptoms, a cystoscopy should be carried out, even many years afterwards.

The results of the present long-term follow-up study of patients with primary or recurrent SUI and concomitant procedures undergoing TVT operation are encouraging. The TVT shows excellent durable subjective and objective cure rates in SUI patients, and shows similar durable objective efficacy for SUI component of MUI patients. However, a long-term subjective cure might not be achieved by this procedure in MUI patients, even when they predominantly complain of SUI. The long-term complications of the TVT are very few.

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## Conflict of interest

None declared.

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## Appendix 1. Urinary Incontinence Severity Score (UISS)

1. Do you experience urine leakage not related to effort or position (for example lying down)?	Not at all	Sometimes	Often
2. Do you experience urine leakage to minor physical activity (e.g. walking or rising)?	Not at all	Sometimes	Often
3. Do you experience urine leakage related to sudden, strong physical activity or even coughing or sneezing?	Not at all	Sometimes	Often
4. Has urine leakage disturbed your daily chores (shopping, cooking, housecleaning etc.)?	Not at all	Sometimes	Often
5. Has urine leakage disturbed your employment (client service, work performance etc.)?	Not at all	Sometimes	Often
6. Are you afraid that others will notice your problem (fear of your odour or wetness etc.)?	Not at all	Sometimes	Often
7. Do you have to restrict or give up social activities (such as visiting friends, physical activity, theatre, church etc.)?	Not at all	Sometimes	Often
8. Do your incontinence symptoms disturb your sex life?	Not at all	Sometimes	Often
9. Does incontinence cause irritation of your external genital organs?	Not at all	Sometimes	Often
10. How often must you use a protective happy or pad?	Not at all	Sometimes	Often

## Appendix 2. Detrusor Instability Score (DIS)

Please circle the most suitable response to the questions below.

	0	1	2
1. How many times per day do you urinate?	5–7	8–10	Over 10
2. How many times at night do you have to get up to urinate?	0–1	2–3	Over 3
3. Do you feel there is still urine in the bladder after urinating?	No	Sometimes	Often
4. Does hurry and tension cause urge to urinate?	No	Slightly	Strongly
5. Do you have urinary leakage during stress (coughing, sneezing, laughing)?	Yes		On other occasions as well
6. Does the leakage of urine happen immediately in connection with stress?	Immediately		After some time
7. Do you feel need to urinate before the leakage of urine?	No	Slightly	Strongly
8. Have you had treated urinary infections during the past two years?	No	1–2	More than 2/chronically
9. How much is the amount of urinary leakage at a time?	Drops	A certain amount	Bladder empties completely
10. Can you stop the stream of urine while urinating?	Yes	Fairly well	No



**Notice of FDA Warning regarding the use of vaginal mesh:**

The U.S. Food and Drug Administration (FDA) has issued several safety communications about the use of mesh for pelvic organ prolapse (POP). However, this AUA guideline reviews the current literature regarding SUI alone, and covers neither POP nor mini-incision slings. The FDA warning does not apply to biologicals used in POP. Based on continuing adverse event reports that have been received by the FDA since their initial warning in 2008, the FDA has stated that serious complications associated with surgical mesh in transvaginal POP repairs are not rare.

The AUA will continue to monitor the FDA's alerts and notices and will update the guideline as additional warnings or alerts regarding this device are issued. Informed consent requires that patients be advised of the risks of vaginal mesh.

The FDA will provide updates on its Web page:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm>.

# Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update

## **Female Stress Urinary Incontinence Guideline Update Panel:**

Rodney A. Appell, MD, Chair  
Roger R. Dmochowski, MD, Facilitator  
Jerry M. Blaivas, MD  
E. Ann Gormley, MD  
Mickey M. Karram, MD  
Saad Juma, MD  
Deborah J. Lightner, MD  
Karl M. Luber, MD  
Eric Scott Rovner, MD  
David R. Staskin, MD  
J. Christian Winters, MD

## **Consultants:**

Hanan S. Bell, PhD  
Patrick M. Florer  
Linda Whetter, DVM, PhD

## **AUA Staff:**

Heddy Hubbard, PhD, MPH  
Edith Budd  
Suzanne Pope, MBA  
Michael Folmer  
Katherine Moore  
Cynthia Janus, MLS  
Kadiatu Kebe



**American  
Urological  
Association**

Education and Research, Inc.

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## ***Introduction***

Stress urinary incontinence (SUI) has a significant impact on the quality of life for many women, although estimates of prevalence vary widely due to inconsistencies in the definitions of SUI and differences in populations studied.<sup>1</sup> A large meta-analysis reported an estimated prevalence for urinary incontinence of 30% in women aged 30 to 60 years, with approximately half of the cases attributed to SUI;<sup>2</sup> another study reported the prevalence of SUI was 5% to 30% in European women.<sup>3</sup> Many women in the United States (U.S.) elect to have a surgical procedure for management of their SUI symptoms each year. The first Female Stress Urinary Incontinence Clinical Guidelines Panel reviewed literature available up to January 1994 and published its report in 1997.<sup>4</sup> Since that time, a new body of literature has emerged on primarily novel surgical interventions for the treatment of SUI. For these reasons, the American Urological Association (AUA) has elected to update the initial report on the Surgical Management of Stress Urinary Incontinence. The literature search used in this analysis had a conclusion date of June 2005; it is recognized that this guideline will likely change in response to new information and further developments in the field.

In the 1997 guideline, the index patient was an otherwise healthy female patient with SUI without significant pelvic organ prolapse. It has become apparent since the prior guideline that many women with SUI also have pelvic organ prolapse and that these two issues may be addressed concurrently. Therefore, in constructing this guideline update, the index patient is defined as an otherwise healthy female patient who has elected surgical therapy for the correction of SUI as in the previous guideline. An additional index patient defined by the panel is an otherwise healthy female patient with SUI and prolapse who elects to have treatment of her

SUI along with surgical correction of prolapse. The current Female Stress Urinary Incontinence Guideline Update Panel (the Panel) was selected by the Panel chair and approved by the Practice Guidelines Committee (PGC) of the AUA. The Panel members are representative of different medical specialties and geographic regions of the U.S. and are from both academic and private institutions.

This report describes an analysis of efficacy and safety outcomes for surgical procedures for use in treatment of SUI and provides a guideline based on review of these data and/or panel consensus. It also offers a discussion about the diagnostic evaluation of the index patient and recommendations for outcomes reporting and future research.

## ***Definitions***

Stress urinary incontinence is a symptom that refers to leakage of urine during events that result in increased abdominal pressure such as sneezing, coughing, physical exercise, lifting, bending and even changing positions. There are two principle causes of this symptom – SUI and the rarer stress-induced detrusor overactivity (involuntary detrusor contractions that are caused by sudden increases in abdominal pressure). The distinction between these two can be determined by (in order of increasing specificity) patient history, physical examination (e.g., urinary loss after a stress event) and urodynamic studies. For the purposes of this guideline, it is assumed that patients in the extracted studies had surgical management of SUI.

Urgency refers to a sudden, compelling desire to pass urine which is difficult to defer<sup>5</sup> or a strong need to pass urine for fear of leakage.<sup>6</sup> Urge urinary incontinence is defined as

involuntary leakage accompanied by or immediately preceded by urgency.<sup>5</sup> Mixed incontinence refers to SUI that occurs in combination with urge urinary incontinence.

### ***Index patient***

The index patient is defined as an otherwise healthy female patient who has elected surgical therapy for the correction of SUI as in the previous guideline. An additional index patient defined by the panel is an otherwise healthy female patient with SUI and pelvic organ prolapse who elects to have treatment of her SUI along with surgical correction of pelvic organ prolapse. Either index patient may be untreated or previously surgically-treated and may have urethral hypermobility and/or intrinsic sphincter deficiency. Urethral hypermobility was defined by the author; no uniform definition was used.

### ***Methodology***

This guideline included analysis of those relevant factors (perceived risks and outcomes of the interventions, patient preferences and relative priorities of the interventions given limited health care resources) used to choose among alternative treatment interventions.<sup>7</sup> The peer-reviewed medical literature was meta-analyzed to estimate outcomes of treatment modalities, and Panel members themselves served as proxies for patients in considering preferences. The steps taken to develop this guideline, further detailed in Chapter 2, included problem definition, literature search, data extraction, systematic evidence combination, guideline generation, approval and dissemination. The Panel did not review needle suspensions or anterior colporrhaphy in

developing this guideline update. Since development of the 1997 guideline, very limited new data has been published addressing these procedures, and there is a lack of current use or interest in them as well. Though these operations may still be performed in isolated circumstances by some surgeons, the Panel believes that they are largely of historical interest only and no longer considers these procedures contemporary treatments for SUI.

### **Problem Definition**

This guideline update was based on the original AUA Guideline on the Surgical Management of Female Stress Urinary Incontinence published in 1997 using a similar methodology. The analysis was likewise limited to surgical treatments but included new procedures and those considered the most efficacious as determined by the previous analysis. Unlike the 1997 guideline, outcomes of surgical therapies for prolapse were also included.

Surgical efficacy was defined in three parts: 1) the resolution and lack of recurrence of SUI and urgency; 2) the resolution of prolapse and the lack of recurrence or new onset of prolapse; and 3) the incidence and severity of adverse events of these treatments. Urgency (resolution and de novo) was included as an efficacy outcome due to its significant impact on patient quality of life. The treatments included in the analysis were retropubic suspensions, slings, injection therapy and artificial sphincters; the analysis excluded those procedures not generally available in the U.S. or not expected to be approved at the time of publication. Anterior repairs for prolapse reduction in conjunction with other surgical treatments for incontinence were included as prolapse surgeries. Procedures used to correct prolapse included hysterectomy in conjunction with or as a component of surgical treatment of SUI and site-specific repairs.



### **Literature Search and Data Extraction**

A database was generated that included articles retrieved for the previous guideline and those resulting from a series of four MEDLINE® searches beginning in December 2002 and concluding in June 2005. The searches were limited to papers involving human subjects and published in the English language on or after 1990 which included the MeSH term “female.” The MeSH headings used were “urinary incontinence, stress,” “stress incontinence” and “urinary incontinence” in any field. A total of 7,111 citations and abstracts were reviewed for relevance by the panel chairs, of which 1,302 citations entered the extraction process. Panel members extracted data from the articles which were then entered into a Microsoft Access® (Microsoft, Redmond, WA) database. In person and via conference calls, the Panel collectively reviewed the extracted data. A total of 436 articles were suitable for inclusion in the meta-analysis; an additional 155 articles were deemed suitable only for their complications data due to an insufficient follow-up duration for the efficacy outcomes analysis.

### **Evidence Combination**

To generate outcomes tables, estimates of the probabilities and/or magnitudes of the outcomes are required for each intervention. Ideally, these come from a synthesis or combination of the evidence. Combination can be performed in a variety of ways depending on the nature and quality of the evidence. For this guideline, the panel used the confidence profile method,<sup>8,9</sup> which provides methods for meta-analyzing data from studies that are not randomized controlled trials (RCTs). Meta-analysis was performed using the Fast\*Pro software to combine individual arms from controlled trials and clinical series where similar patients were similarly treated. Although a number of RCTs were found through the literature search, there were insufficient numbers on any one topic to warrant an independent meta-analysis of RCTs. The results of

certain trials are discussed where relevant. Frequently, published series used in a combined analysis showed very divergent results implying site-to-site variations, variability in patient populations, in the performance of the intervention, the skill of the surgeon or normal statistical variation. Given these differences, a random-effects, or hierarchical, model was used to combine the studies.

### **Patient Groups**

While stratifying outcomes based on patient characteristics such as type of incontinence, previous treatment(s), presence of prolapse, prior pregnancy and severity of incontinence would be most instructive, in most cases the outcomes data were not fully or consistently identified by these criteria. Therefore, analysis was limited to two patient groups; one in which no patient received concomitant surgical treatment for prolapse (comparable to the previous guideline) and another in which some or all patients received concomitant treatment for prolapse. Very few published studies included all of the SUI patients receiving concomitant prolapse treatment, therefore, the analysis was based mainly on data from studies that included some patients with prolapse treatment. This did not permit a clear distinction to be made between these groups in the analysis. An attempt to stratify the outcomes of SUI surgical interventions by the presence of prolapse was thwarted by insufficient data since few published studies stratified results in this manner.

### **Efficacy Analysis**

The efficacy outcomes analyzed included two levels of continence: cured/dry and cured/dry/improved; these are reported percentages and credible intervals (Bayesian confidence intervals [CIs]). Allocation to the previously mentioned categories was determined by author definition of continence. For the analysis of postoperative urgency, patients were divided into

three categories: without pre-existing urgency, with pre-existing urgency, and unknown or uncertain pre-existing urgency. Postoperative urgency categories included urge incontinence, urge symptoms and unspecified. Again, the results are reported as the percent of the relevant patient group having each outcome. Abbreviated tables summarizing the cured/dry and resolution or urge incontinence for the time interval of 12-23 months for patients with or without concurrent prolapse treatment are provided with this document (see Tables 1–3); for a complete set of data tables see Appendices A7-A16.

### **Complications**

Complications were analyzed similarly to the efficacy outcomes. However, because of the wide variety of ways authors name and describe complications, the panel attempted to group complications together that represented the same or related outcomes. As discussed in Chapter 2, this could result in some inaccuracies in the resultant estimates. Appendix A-17 shows how the panel grouped outcomes. Certain complication outcomes such as pain and de novo urgency were tabulated as defined by the author, and no further analysis was performed based upon the limitations of data reporting. After grouping the complications for analysis, the grouped complications were then put into general categories for display and discussion. Outcomes tables were developed for each group of complications. Separate tables were again created for patients with and without prolapse treatment. The format of the tables is the same as the efficacy tables. An abbreviated table summarizing retention data for patients with or without concurrent prolapse treatment is provided with this document (see Table 4); for a complete set of data tables see Appendices A7 – A16.

# Appendix A11 -Complications rates.Any Prolapse

## SUI Guideline Update Panel Complications ANY Prolapse\*\*

### Death

### Transfusion

### General Medical Complications

Cardiovascular  
Febrile  
Infection  
Infection/Local Extension  
Neurologic  
Pulmonary  
Systemic - Abscess  
UTI

Suspensions								
All Retropubic Suspensions			Burch Suspension			Laparoscopic Suspension		
G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
7/415	6%	(2 - 14)%	6/375	7%	(2 - 16)%	5/183	2%	(1 - 6)%
3/342	2%	(1 - 4)%	3/342	2%	(1 - 4)%	3/185	3%	(1 - 6)%
7/614	11%	(5 - 20)%	5/513	14%	(6 - 26)%	3/296	2%	(1 - 5)%
2/280	12%	(6 - 19)%	2/280	12%	(6 - 19)%			
1/51	3%	(1 - 7)%	1/51	3%	(1 - 7)%	2/164	3%	(1 - 9)%
1/33	4%	(0 - 13)%				2/151	3%	(1 - 7)%
1/82	4%	(1 - 9)%	1/82	4%	(1 - 9)%	2/149	3%	(1 - 8)%
10/779	17%	(11 - 25)%	10/779	17%	(11 - 25)%	11/545	7%	(5 - 11)%

### Operative Complications

Bladder Injury  
Bleeding  
Bleeding - Acute  
Bleeding - Hematoma  
Bowel Injury  
Erosion Extrusion  
Erosion Extrusion - Unknown  
Erosion Extrusion - Urethral-Bladder  
Erosion Extrusion - Vaginal  
Nerve Injury  
Operative CX - Other  
Osteomyelitis  
Ureteral Injury  
Urethral Injury  
Urinary Tract Injury NS  
Vaginal Operative CX  
Wound  
Abdominal  
Vaginal

8/503	3%	(2 - 6)%	8/503	3%	(2 - 6)%	16/901	6%	(4 - 8)%
2/177	5%	(1 - 13)%	2/177	5%	(1 - 13)%	2/98	2%	(0 - 8)%
9/600	5%	(3 - 7)%	8/560	5%	(3 - 7)%	7/366	3%	(2 - 6)%
2/150	2%	(0 - 6)%	1/82	1%	(0 - 6)%	3/182	3%	(1 - 8)%
2/147	2%	(0 - 5)%	2/147	2%	(0 - 5)%	4/201	6%	(2 - 11)%
1/127	1%	(0 - 4)%	1/127	1%	(0 - 4)%	1/36	1%	(0 - 7)%
2/2	71%	(23 - 98)%		*				
	*			*		3/109	4%	(1 - 10)%
	*			*				
						1/113	1%	(0 - 4)%
5/408	5%	(3 - 9)%	5/408	5%	(3 - 9)%	4/206	4%	(1 - 8)%
3/233	5%	(1 - 12)%	1/132	1%	(0 - 3)%	4/155	7%	(2 - 18)%
						1/48	0%	(0 - 5)%

### Subjective Complications

Pain  
Sexual Dysfunction  
Voiding Dysfunction

2/76	9%	(2 - 24)%	2/76	9%	(2 - 24)%	7/353	3%	(2 - 6)%
5/262	7%	(4 - 12)%	5/262	7%	(4 - 12)%	1/34	12%	(4 - 26)%
3/314	16%	(5 - 33)%	3/314	16%	(5 - 33)%	3/104	8%	(3 - 15)%

### Conversion

						3/219	11%	(5 - 20)%
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### Other Complications

3/183	8%	(4 - 14)%	3/183	8%	(4 - 14)%	1/36	6%	(1 - 17)%
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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

\*\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

**Appendix A11 -Complications rates.Any Prolapse****SUI Guideline Update Panel  
Complications  
ANY Prolapse\*\*****Death****Transfusion****General Medical Complications**

Cardiovascular

Febrile

Infection

Infection/Local Extension

Neurologic

Pulmonary

Systemic - Abscess

UTI

**Operative Complications**

Bladder Injury

Bleeding

Bleeding - Acute

Bleeding - Hematoma

Bowel Injury

Erosion Extrusion

Erosion Extrusion - Unknown

Erosion Extrusion - Urethral-Bladder

Erosion Extrusion - Vaginal

Nerve Injury

Operative CX - Other

Osteomyelitis

Ureteral Injury

Urethral Injury

Urinary Tract Injury NS

Vaginal Operative CX

Wound

Abdominal

Vaginal

**Subjective Complications**

Pain

Sexual Dysfunction

Voiding Dysfunction

**Conversion****Other Complications****Slings****Autologous fascia****without Bone Anchors**

G/P Med CI (2.5 - 97.5)%

1/198 4% (2 - 7)%

**Autologous Vaginal Wall Slings****with/without Bone anchors**

G/P Med CI (2.5 - 97.5)%

2/35 9% (2 - 24)%

**w Bone Anchors - Suprapubic**

G/P Med CI (2.5 - 97.5)%

			1/15	8%	(1 - 27)%		
1/80	4%	(1 - 10)%	2/32	22%	(8 - 42)%		
1/80	10%	(5 - 18)%					
1/80	8%	(3 - 15)%	1/20	1%	(0 - 12)%		

2/278	8%	(1 - 26)%	1/82	3%	(1 - 8)%		
1/80	8%	(3 - 15)%	1/20	6%	(1 - 21)%		
1/80	1%	(0 - 6)%					
*			1/20	1%	(0 - 12)%		
			1/82	1%	(0 - 6)%		
			1/20	1%	(0 - 12)%		*
2/278	4%	(2 - 8)%					
			1/82	3%	(1 - 8)%		*
			2/65	3%	(0 - 11)%		

1/80	3%	(1 - 8)%	1/45	3%	(0 - 10)%		


Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

\*\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

### Appendix A11 -Complications rates.Any Prolapse

**SUI Guideline Update Panel**  
**Complications**  
**ANY Prolapse\*\***

## Slings

**Death**

### Transfusion

### General Medical Complications

- Cardiovascular
- Febrile
- Infection
- Infection/Local Extension
- Neurologic
- Pulmonary
- Systemic - Abscess
- UTI

[illegible]

### Operative Complications

Bladder Injury  
Bleeding  
Bleeding - Acute  
Bleeding - Hematoma  
Bowel Injury  
Erosion Extrusion  
Erosion Extrusion - Unknown  
Erosion Extrusion - Urethral-Bladder  
Erosion Extrusion - Vaginal  
Nerve Injury  
Operative CX - Other  
Osteomyelitis  
Ureteral Injury  
Urethral Injury  
Urinary Tract Injury NS  
Vaginal Operative CX  
Wound  
Abdominal  
Vaginal

[illegible]

## Subjective Complications

**Pain**  
**Sexual Dysfunction**  
**Voiding Dysfunction**


## Conversion

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### Other Complications

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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients In those group

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

**\*\*By any evaluation method, including subjective and objective; Includes groups/arms in which ANY patient had a concurrent prolapse treatment.**



**Appendix A11 -Complications rates.Any Prolapse****SUI Guideline Update Panel  
Complications  
ANY Prolapse\*\*****Slings****Synthetic at Bladder Neck****Death****Transfusion****General Medical Complications**

Cardiovascular

Febrile

Infection

Infection/Local Extension

Neurologic

Pulmonary

Systemic - Abscess

UTI

with Bone Anchors			w Bone Anchors - Suprapubic			without Bone Anchors		
G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
						2/92	53%	(40 - 66)%

						1/47	2%	(0 - 10)%
			1/49	0%	(0 - 5)%	1/20	25%	(10 - 46)%
						3/112	9%	(4 - 17)%

**Operative Complications**

Bladder Injury

Bleeding

Bleeding - Acute

Bleeding - Hematoma

Bowel Injury

Erosion Extrusion

Erosion Extrusion - Unknown

Erosion Extrusion - Urethral-Bladder

Erosion Extrusion - Vaginal

Nerve Injury

Operative CX - Other

Osteomyelitis

Ureteral Injury

Urethral Injury

Urinary Tract Injury NS

Vaginal Operative CX

Wound

Abdominal

Vaginal

						1/24	1%	(0 - 10)%
						3/112	11%	(3 - 24)%
						2/143	12%	(2 - 36)%
			1/49	2%	(0 - 9)%	1/20	1%	(0 - 12)%
			1/49	0%	(0 - 5)%	4/223	9%	(5 - 19)%
						1/98	1%	(0 - 12)%
						1/98	20%	(14 - 30)%
						1/98	40%	(31 - 50)%
						1/98	26%	(18 - 35)%
						1/20	1%	(0 - 12)%

**Subjective Complications**

Pain

Sexual Dysfunction

Voiding Dysfunction

		1/49	4%	(1 - 12)%	1/62	2%	(0 - 7)%
		1/49	4%	(1 - 12)%			
		1/49	0%	(0 - 5)%	2/122	16%	(3 - 38)%

**Conversion****Other Complications**

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

\*\*By any evaluation method, including subjective and objective; Includes groups/arms in which ANY patient had a concurrent prolapse treatment.



## Appendix A11 -Complications rates.Any Prolapse

SUI Guideline Update Panel  
Complications  
ANY Prolapse\*\*

## Slings

## Xenograft

## Synthetic at Midurethra      without Bone Anchors      Other Sling

G/P    Med    CI (2.5 - 97.5)%    G/P    Med    CI (2.5 - 97.5)%    G/P    Med    CI (2.5 - 97.5)%

Death

Transfusion

## General Medical Complications

Cardiovascular

Febrile

Infection

Infection/Local Extension

Neurologic

Pulmonary

Systemic - Abscess

UTI

2/2113	0%	(0 - 1)%						
3/468	8%	(4 - 14)%						
1/1455	1%	(0 - 1)%	1/18	17%	(5 - 38)%			
	*							
1/75	2%	(0 - 6)%						
2/111	3%	(1 - 9)%	1/10	60%	(30 - 85)%			
16/3016	7%	(5 - 9)%				1/126	1%	(0 - 4)%

## Operative Complications

Bladder Injury

Bleeding

Bleeding - Acute

Bleeding - Hematoma

Bowel Injury

Erosion Extrusion

Erosion Extrusion - Unknown

Erosion Extrusion - Urethral-Bladder

Erosion Extrusion - Vaginal

Nerve Injury

Operative CX - Other

Osteomyelitis

Ureteral Injury

Urethral Injury

Urinary Tract Injury NS

Vaginal Operative CX

Wound

Abdominal

Vaginal

29/4248	6%	(5 - 8)%				1/126	3%	(1 - 6)%
6/1921	2%	(1 - 3)%				1/126	0%	(0 - 2)%
15/3770	3%	(2 - 4)%						
	*							
6/632	4%	(2 - 7)%						
5/308	3%	(1 - 8)%						
6/2185	2%	(1 - 5)%						
3/1891	1%	(0 - 2)%						
5/1801	2%	(1 - 3)%				1/126	0%	(0 - 2)%
3/393	1%	(0 - 3)%	1/18	17%	(5 - 38)%	1/126	5%	(2 - 10)%
2/301	2%	(0 - 6)%						
3/1612	1%	(0 - 2)%						
1/45	1%	(0 - 5)%						

## Subjective Complications

Pain

Sexual Dysfunction

Voiding Dysfunction

4/1985	3%	(1 - 7)%						
9/2407	16%	(6 - 33)%						

## Conversion

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## Other Complications

1/193	1%	(0 - 2)%						
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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

\*\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

**Appendix A11 -Complications rates.Any Prolapse****SUI Guideline Update Panel****Complications****ANY Prolapse\*\***

Injectables			Artificial Sphincter		
Collagen					
G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%

**Death****Transfusion****General Medical Complications**

Cardiovascular  
 Febrile  
 Infection  
 Infection/Local Extension  
 Neurologic  
 Pulmonary  
 Systemic - Abscess  
 UTI

			1/206	1%	(0 - 3)%
1/105	2%	(0 - 6)%			

**Operative Complications**

Bladder Injury  
 Bleeding  
 Bleeding - Acute  
 Bleeding - Hematoma  
 Bowel Injury  
 Erosion Extrusion  
 Erosion Extrusion - Unknown  
 Erosion Extrusion - Urethral-Bladder  
 Erosion Extrusion - Vaginal  
 Nerve Injury  
 Operative CX - Other  
 Osteomyelitis  
 Ureteral Injury  
 Urethral Injury  
 Urinary Tract Injury NS  
 Vaginal Operative CX  
 Wound  
 Abdominal  
 Vaginal

			2/206	15%	(10 - 22)%
			1/179	4%	(2 - 8)%
			1/206	7%	(4 - 11)%
			1/206	3%	(1 - 6)%
			2/206	2%	(0 - 9)%
			2/206	13%	(6 - 22)%
			1/179	7%	(4 - 12)%

**Subjective Complications**

Pain  
 Sexual Dysfunction  
 Voiding Dysfunction


**Conversion**

--	--	--	--	--	--

**Other Complications**

			1/206	3%	(2 - 7)%
--	--	--	-------	----	----------

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

\*\*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

## Appendix A16 -Complications rates - No Prolapse

### SUI Guideline Update Panel

### Complications

### NO Prolapse

	Suspensions								
	All Retropubic Suspensions			Burch Suspension			Laparoscopic Suspension		
	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death	2/170	3%	(0 - 14)%	2/170	3%	(0 - 14)%			
Transfusion	6/321	6%	(2 - 12)%	4/169	9%§	(3 - 19)%	1/24	5%	(0 - 18)%

### General Medical Complications

Cardiovascular	6/592	2%	(1 - 4)%	3/294	3%	(1 - 8)%			
Dermatologic									
Febrile	7/426	8%	(5 - 12)%	3/113	11%	(5 - 20)%	1/60	0%	(0 - 4)%
Infection	1/98	2%	(0 - 6)%	1/98	2%	(0 - 6)%	1/31	4%	(0 - 14)%
Infection/Local Extension		*			*				
Neurologic	1/113	1%	(0 - 4)%	1/113	1%	(0 - 4)%			
Pulmonary	1/15	8%	(1 - 27)%				1/51	2%	(0 - 9)%
Systemic - Abscess	1/62	7%	(2 - 15)%	1/62	7%	(2 - 15)%			
UTI	17/1442	13%	(9 - 19)%	10/978	15%	(8 - 24)%	1/51	2%	(0 - 9)%

### Operative Complications

Bladder Injury	10/887	4%	(2 - 7)%	7/589	6%	(2 - 12)%	5/165	5%	(2 - 10)%
Bleeding									
Bleeding - Acute	3/433	4%	(1 - 9)%	2/334	2%	(0 - 6)%			
Bleeding - Hematoma	6/484	3%	(2 - 6)%	5/469	3%	(1 - 5)%	1/51	2%	(0 - 9)%
Bowel Injury	1/31	4%	(0 - 14)%	1/31	4%	(0 - 14)%	1/31	4%	(0 - 14)%
Erosion Extrusion - Unknown									
Erosion Extrusion - Urethral-Bladder	2/102	19%§	(1 - 70)%		*				
Erosion Extrusion - Vaginal									
Nerve Injury									
Osteomyelitis		*							
Ureteral Injury	5/1739	1%	(1 - 2)%	4/1640	1%	(1 - 2)%	3/57	11%	(1 - 42)%
Urethral Injury							2/55	2%	(0 - 10)%
Urinary Tract Injury NS	1/60	2%	(0 - 8)%						
Vaginal Operative CX									
Wound	13/1229	6%	(4 - 7)%	8/793	6%	(4 - 9)%	1/51	2%	(0 - 9)%
Wound - Abdominal	9/761	4%	(3 - 6)%	5/449	4%	(2 - 7)%			
Wound - Vaginal									

### Subjective Complications

Pain	9/980	5%	(3 - 8)%	6/756	6%	(3 - 12)%		*	
Sexual Dysfunction	8/989	4%	(2 - 6)%	5/801	3%	(2 - 4)%			
Voiding Dysfunction	6/636	9%	(5 - 15)%	5/583	10%	(5 - 18)%	1/60	5%	(1 - 13)%

### Conversion

1/17	7%	(1 - 24)%	1/17	7%	(1 - 24)%	3/184	5%	(2 - 9)%
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### Other Complications

3/253	5%	(0 - 20)%	2/154	14%	(0 - 66)%	1/51	2%	(0 - 9)%
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Note: G/P: G = Number of Groups/Treatment arms extracted P = Number of Patients in those groups

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

## Appendix A16 -Complications rates - No Prolapse

### SUI Guideline Update Panel Complications NO Prolapse

			Slings								
			Autologous fascia			Autologous Vaginal Wall Slings			Cadaveric		
			without Bone Anchors			with/without Bone anchors			without Bone Anchors		
			G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death			1/90	0%	(0 - 3)%						
Transfusion			3/194	4%	(1 - 11)%				1/63	0%	(0 - 4)%
General Medical Complications											
Cardiovascular			2/338	2%	(0 - 5)%						
Dermatologic											
Febrile											
Infection			1/71	0%	(0 - 3)%				1/63	7%	(2 - 14)%
Infection/Local Extension											
Neurologic			1/30	4%§	(0 - 15)%						
Pulmonary			1/91	1%	(0 - 5)%						
Systemic - Abscess									1/104	2%	(0 - 6)%
UTI			5/241	16%	(6 - 31)%	2/402	4%	(2 - 7)%	1/63	7%	(2 - 14)%
Operative Complications											
Bladder Injury			6/423	4%	(2 - 9)%	1/29	1%	(0 - 8)%			
Bleeding											
Bleeding - Acute			1/20	6%	(1 - 21)%						
Bleeding - Hematoma			1/247	1%	(0 - 3)%				1/104	1%	(0 - 4)%
Bowel Injury											
Erosion Extrusion - Unknown			1/33	1%	(0 - 7)%					*	
Erosion Extrusion - Urethral-Bladder			4/370	2%	(0 - 7)%				1/63	0%	(0 - 4)%
Erosion Extrusion - Vaginal						1/373	2%	(1 - 4)%		*	
Nerve Injury									1/104	1%	(0 - 4)%
Osteomyelitis											
Ureteral Injury											
Urethral Injury											
Urinary Tract Injury NS											
Vaginal Operative CX											
Wound			2/111	8%	(3 - 16)%						
Wound - Abdominal			1/247	1%	(0 - 3)%	2/402	5%	(3 - 8)%			
Wound - Vaginal											
Subjective Complications											
Pain			3/63	10%	(1 - 35)%						
Sexual Dysfunction			4/105	8%	(3 - 16)%						
Voiding Dysfunction				*					1/8	38%§	(12 - 71)%
Conversion											
Other Complications											

Note: G/P: G = Number of Groups/Treatment arms extracted P = Number of Patients in those groups

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

## Appendix A16 -Complications rates - No Prolapse

### SUI Guideline Update Panel Complications NO Prolapse

Slings								
Synthetic at Bladder Neck								
with Bone Anchors			w Bone Anchors - Suprapubic			w Bone Anchors - Transvaginal		
G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
Death								
Transfusion								
General Medical Complications								
Cardiovascular								
Dermatologic								
Febrile								
Infection								
Infection/Local Extension								
Neurologic								
Pulmonary								
Systemic - Abscess								
UTI								

### Operative Complications

Bladder Injury	1/11	10%§	(1 - 35)%				
Bleeding							
Bleeding - Acute							
Bleeding - Hematoma							
Bowel Injury							
Erosion Extrusion - Unknown							
Erosion Extrusion - Urethral-Bladder						*	
Erosion Extrusion - Vaginal	1/10	21%§	(4 - 50)%			*	
Nerve Injury							
Osteomyelitis		*		1/108	3%	(1 - 7)%	
Ureteral Injury							
Urethral Injury							
Urinary Tract Injury NS							
Vaginal Operative CX							
Wound							
Wound - Abdominal							
Wound - Vaginal							

### Subjective Complications

Pain					
Sexual Dysfunction					
Voiding Dysfunction					

### Conversion

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### Other Complications

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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients In those groups

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

**Appendix A16 -Complications rates - No Prolapse****SUI Guideline Update Panel  
Complications  
NO Prolapse****Slings****Synthetic at Bladder Neck**

without Bone Anchors			Synthetic at Midurethra			Other Sling		
G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
			1/25	1%	(0 - 9)%			
1/200	1%	(0 - 3)%	3/569	2%	(1 - 4)%			

**Death****Transfusion****General Medical Complications**

Cardiovascular  
Dermatologic  
Febrile  
Infection  
Infection/Local Extension  
Neurologic  
Pulmonary  
Systemic - Abscess  
UTI

			2/261	1%	(0 - 3)%			
							*	
			2/174	7%	(4 - 13)%			
2/315	3%	(1 - 5)%	1/25	1%	(0 - 9)%			
2/224	10%	(2 - 27)%	9/771	8%	(5 - 13)%			

**Operative Complications**

Bladder Injury  
Bleeding  
Bleeding - Acute  
Bleeding - Hematoma  
Bowel Injury  
Erosion Extrusion - Unknown  
Erosion Extrusion - Urethral-Bladder  
Erosion Extrusion - Vaginal  
Nerve Injury  
Osteomyelitis  
Ureteral Injury  
Urethral Injury  
Urinary Tract Injury NS  
Vaginal Operative CX  
Wound  
Wound - Abdominal  
Wound - Vaginal

1/200	1%	(0 - 2)%	23/1925	6%	(4 - 8)%			
			6/705	3%	(1 - 5)%			
			7/1035	3%	(2 - 4)%			
			3/256	1%	(0 - 4)%			
2/501	17%§	(9 - 28)%	6/621	1%	(0 - 3)%			
3/346	3%	(1 - 9)%						
6/591	8%	(4 - 15)%	9/891	7%	(2 - 15)%		*	
1/200	1%	(0 - 2)%	1/404	0%	(0 - 1)%			
				*			*	
			2/302	2%	(0 - 7)%			
2/385	7%	(3 - 14)%	3/280	2%	(1 - 5)%			
			2/75	2%	(0 - 8)%			
			4/189	4%	(1 - 7)%			

**Subjective Complications**

Pain  
Sexual Dysfunction  
Voiding Dysfunction

2/264	9%	(2 - 23)%	2/512	1%	(0 - 3)%			
			1/62	0%	(0 - 4)%			
			1/1175	2%	(1 - 3)%			

**Conversion**

							*	
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**Other Complications**

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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients In those groups

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.



### Appendix A16 -Complications rates - No Prolapse

## SUI Guideline Update Panel Complications

## NO Prolapse

[illegible]

### General Medical Complications

Cardiovascular					
Dermatologic	3/399	5%	(1 - 17)%		
Febrile					
Infection					
Infection/Local Extension					
Neurologic					
Pulmonary	1/60	2%	(0 - 8)%		
Systemic - Abscess	1/115	1%	(0 - 4)%		
UTI	6/381	10%	(5 - 17)%		

## Operative Complications

Bladder Injury					
Bleeding					
Bleeding - Acute	4/251	5%	(3 - 8)%		
Bleeding - Hematoma					
Bowel Injury					
Erosion Extrusion - Unknown				1/18	28%§ (11 - 51)%
Erosion Extrusion - Urethral-Bladder					
Erosion Extrusion - Vaginal					
Nerve Injury					
Osteomyelitis					
Ureteral Injury					
Urethral Injury		*		*	
Urinary Tract Injury NS					
Vaginal Operative CX					
Wound					
Wound - Abdominal					
Wound - Vaginal					

### Subjective Complications

Pain					
Sexual Dysfunction					
Voiding Dysfunction					

## Conversion

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### Other Complications

3/342	27%§	(2-76)%			1/18	23%§	(8-45)%
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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

\* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.



## UROGYNECOLOGY

# Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis

Megan O. Schimpf, MD; David D. Rahn, MD; Thomas L. Wheeler, MD, MSPH; Minita Patel, MD, MS; Amanda B. White, MD; Francisco J. Orejuela, MD; Sherif A. El-Nashar, MBBCh, MS; Rebecca U. Margulies, MD; Jonathan L. Gleason, MD; Sarit O. Aschkenazi, MD; Mamta M. Mamik, MD; Renée M. Ward, MD; Ethan M. Balk, MD, MPH; Vivian W. Sung, MD, MPH; for the Society of Gynecologic Surgeons Systematic Review Group

**OBJECTIVE:** Understanding the long-term comparative effectiveness of competing surgical repairs is essential as failures after primary interventions for stress urinary incontinence (SUI) may result in a third of women requiring repeat surgery.

**STUDY DESIGN:** We conducted a systematic review including English-language randomized controlled trials from 1990 through April 2013 with a minimum 12 months of follow-up comparing a sling procedure for SUI to another sling or Burch urethropexy. When at least 3 randomized controlled trials compared the same surgeries for the same outcome, we performed random effects model metaanalyses to estimate pooled odds ratios (ORs).

**RESULTS:** For midurethral slings (MUS) vs Burch, metaanalysis of objective cure showed no significant difference (OR, 1.18; 95% confidence interval [CI], 0.73–1.89). Therefore, we suggest either intervention; the decision should balance potential adverse events (AEs) and concomitant surgeries. For women considering pubovaginal sling vs Burch, the evidence favored slings for both subjective and objective cure. We recommend pubovaginal sling to maximize cure outcomes. For pubovaginal slings vs MUS, metaanalysis of subjective cure favored MUS (OR, 0.40; 95% CI,

0.18–0.85). Therefore, we recommend MUS. For obturator slings vs retropubic MUS, metaanalyses for both objective (OR, 1.16; 95% CI, 0.93–1.45) and subjective cure (OR, 1.17; 95% CI, 0.91–1.51) favored retropubic slings but were not significant. Metaanalysis of satisfaction outcomes favored obturator slings but was not significant (OR, 0.77; 95% CI, 0.52–1.13). AEs were variable between slings; metaanalysis showed overactive bladder symptoms were more common following retropubic slings (OR, 1.413; 95% CI, 1.01–1.98,  $P = .046$ ). We recommend either retropubic or obturator slings for cure outcomes; the decision should balance AEs. For minislings vs full-length MUS, metaanalyses of objective (OR, 4.16; 95% CI, 2.15–8.05) and subjective (OR, 2.65; 95% CI, 1.36–5.17) cure both significantly favored full-length slings. Therefore, we recommend a full-length MUS.

**CONCLUSION:** Surgical procedures for SUI differ for success rates and complications, and both should be incorporated into surgical decision-making. Low- to high-quality evidence permitted mostly level-1 recommendations when guidelines were possible.

**Key words:** Burch urethropexy, midurethral sling, pubovaginal sling, stress urinary incontinence, single-incision sling

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From the Division of Gynecology and Urogynecology, Department of Obstetrics and Gynecology, University of Michigan Medical School, Ann Arbor, MI (Dr Schimpf); Department of Obstetrics and Gynecology, University of Texas Southwestern Medical Center, Dallas, TX (Dr Rahn); Department of Obstetrics and Gynecology, University of South Carolina School of Medicine Greenville, Greenville, SC (Dr Wheeler); Department of Obstetrics and Gynecology, Kaiser Permanente, Roseville, CA (Dr Patel); Department of Obstetrics and Gynecology, University of Texas Southwestern at Seton Healthcare Family, Austin, TX (Dr White); Department of Obstetrics and Gynecology and Reproductive Sciences, University of Texas Health Science Center at Houston, Houston, TX (Dr Orejuela); Division of Gynecologic Surgery, Department of Obstetrics and Gynecology, Mayo Clinic, Rochester, MN (Dr El-Nashar); Division of Urogynecology, Department of Obstetrics and Gynecology, Kaiser Permanente, Oakland, CA (Dr Margulies); Division of Urogynecology, Department of Obstetrics and Gynecology, Carilion Clinic, Roanoke, VA (Dr Gleason); Department of Urogynecology, ProHealth Care, Women's Center, Medical College of Wisconsin, Waukesha, WI (Dr Aschkenazi); Icahn School of Medicine at Mount Sinai, Department of Obstetrics and Gynecology, New York, NY (Dr Mamik); Vanderbilt University Medical Center, Department of Obstetrics and Gynecology, Nashville, TN (Dr Ward); Tufts Medical Center, Institute for Clinical Research and Health Policy Studies, Boston, MA (Dr Balk); and Division of Urogynecology and Reconstructive Pelvic Surgery, Department of Obstetrics and Gynecology, Women and Infants Hospital of Rhode Island and Warren Alpert Medical School of Brown University, Providence, RI (Dr Sung).

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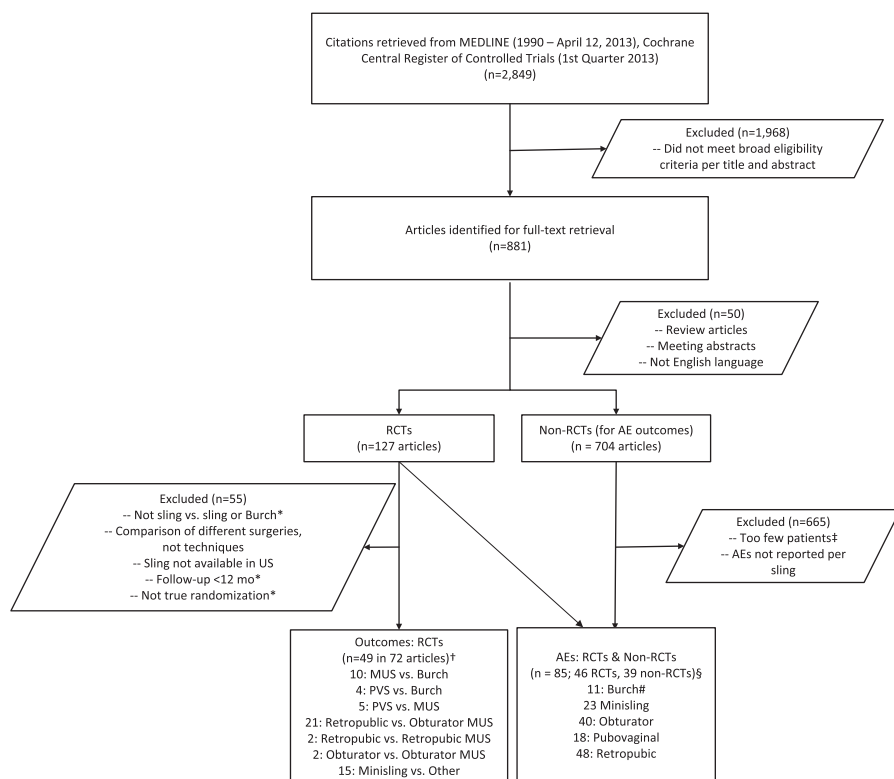
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Reprints: Megan O. Schimpf, MD, Obstetrics and Gynecology, Female Pelvic Medicine and Reconstructive Surgery, University of Michigan, L4000 Women's, 1500 E. Medical Center Dr., Ann Arbor, MI 48109. [mschimpf@umich.edu](mailto:mschimpf@umich.edu).

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**FIGURE 1**  
**Literature flow**



PVS, pubovaginal slings.

\*These studies were potentially eligible to be included for adverse event (AE) analyses; †Several studies had 3 arms and provided data for multiple comparisons; ‡For noncomparative studies, the following minimum sample size criteria were used: minisling obturator,  $n \geq 120$ ; minisling retropubic,  $n \geq 100$ ; obturator midurethral sling (MUS),  $n \geq 1000$ ; pubovaginal fascial,  $n \geq 300$ ; pubovaginal synthetic,  $n \geq 120$ ; retropubic MUS,  $n \geq 1000$ ; §Several studies reported on  $\geq 2$  slings; ¶Only from randomized controlled trials (RCTs).

Schimpf. Sling surgery for stress urinary incontinence. *Am J Obstet Gynecol* 2014.

**S**tress urinary incontinence (SUI), or the involuntary loss of urine with activity such as coughing, laughing, and sneezing, is present in 15–80% of women.<sup>1</sup> Options for treating SUI include physical therapy, pessaries, urethral bulking injections, and surgery. Surgery traditionally consisted of Burch urethropexy or pubovaginal sling. Since 1996, when Ulmsten et al<sup>2</sup> published the initial paper about retropubic tension-free vaginal tape (TVT), the use of synthetic midurethral slings (MUS) has grown to become the most common surgery performed for SUI in women.<sup>3</sup> This type of surgery has evolved to also include options of obturator passage and smaller, single-incision synthetic slings (eg, “minislings”).

The decision of which SUI procedure to perform can include suture-only, native

tissue, mesh, laparoscopic, open incisions, small incisions, or single-incision surgery. Many studies have compared these options. The primary aim of our work was to utilize systematic review and meta-analysis methodology to compare objective and subjective cure rates in adult women with SUI between these different surgeries. The secondary outcomes were to compare surgical methods by quality-of-life measures, sexual function, and perioperative and adverse event (AE) data.

## MATERIALS AND METHODS

The Society of Gynecologic Surgeons Systematic Review Group includes members with clinical and surgical expertise on female SUI and in the conduct of systematic reviews and guideline development. This project was considered exempt from institutional review board approval.

## Data sources and searches

We searched MEDLINE and Cochrane Central Register for Controlled Trials from Jan. 1, 1990 through April 12, 2013 (Figure 1). We excluded older studies because the TVT was not available in the United States prior to this. Search terms included “urinary incontinence,” “urgency,” “sling,” “obturator,” “retropubic,” “pubovaginal,” “vaginal tape,” “urologic surgical procedures” (instrumentation or adverse effects), and related terms. The search was limited to comparative studies, cohort studies, and systematic reviews. The search was further limited to human and English-language studies. Meeting abstracts were excluded. Any review articles obtained in this search were excluded after reference lists were reviewed and articles not originally in the search were obtained. Study authors were not contacted.

Twelve reviewers independently double-screened the abstracts using the computerized screening program Abstrackr (Tufts Medical Center, Boston, MA).<sup>4</sup> To establish relevance and consensus among reviewers, all 12 screened and achieved consensus on an initial batch of 300 abstracts. Potentially relevant full-text articles were also independently double-screened by 12 reviewers.

## Study selection

For the principal evaluation of outcomes, we included peer-reviewed randomized controlled trials (RCTs) with at least 12 months of follow-up (Table 1). Trials were excluded from outcomes analysis for poor randomization schemes, such as alternate assignment of patients or assignment based on day of the week or birth date. We included RCTs that compared  $\geq 2$  sling procedures or a sling procedure to Burch urethropexy performed in adult women for SUI. Studies that compared Burch urethropexy to any other surgery were excluded. Bulking injections were excluded because they are not similar enough to sling surgeries regarding cure, perioperative data, or AEs. When a study included 3 arms, it was analyzed as multiple 2-arm comparisons. For the evaluation of AEs we

TABLE 1

## Randomized controlled trials included in systematic review

Study	Study quality <sup>r</sup>	Intervention	Comparator	n, intervention	n, comparator	Follow-up duration	OC	SC	Po	AE	QoL	SF
MUS vs Burch												
Bai et al, <sup>9</sup> 2005 <sup>a</sup>	B	Retropubic MUS (TVT)	Burch	31	33	12 mo	X			X		
Bandarian et al, <sup>10</sup> 2011	C	Obturator MUS (TOT, unspecified)	Burch	31	31	25 mo mean		X	X	X		
Foote et al, <sup>11</sup> 2006	C	Retropubic MUS (SPARC)	Laparoscopic Burch	49	48	24 mo	X	X	X	X		
Liapis et al, <sup>12</sup> 2002	C	Retropubic MUS (TVT)	Burch	36	35	24 mo	X	X	X	X		
Paraiso et al, <sup>13</sup> 2004 <sup>b</sup>	B	Retropubic MUS (TVT)	Laparoscopic Burch	36	36	21 mo	X	X	X	X	X	
Persson et al, <sup>14</sup> 2002	B	Retropubic MUS (TVT)	Laparoscopic Burch	38	33	12 mo	X	X	X	X		
Sivasloglu et al, <sup>15</sup> 2007	A	Obturator MUS (Safyre T)	Burch	49	51	24 mo	X	X	X	X		
Téllez Martínez-Fornés et al, <sup>16</sup> 2009	B	Retropubic MUS (TVT)	Burch	24	25	36 mo	X	X	X	X	X	
Wang and Chen, <sup>17</sup> 2003	B	Retropubic MUS (TVT)	Burch	49	49	22 mo	X	X	X	X		
Ward et al, <sup>18</sup> 2002 <sup>c</sup>	B	Retropubic MUS (TVT)	Burch	169	175	5 y	X		X	X	X	X
PVS vs Burch												
Albo et al, <sup>19</sup> 2007 (SISTER Trial) <sup>d</sup>	A	PVS (autologous fascia)	Burch	326	329	24 mo	X	X	X	X	X	
Bai et al, <sup>9</sup> 2005 <sup>a</sup>	B	PVS (autologous fascia)	Burch	28	33	12 mo	X			X		
Culligan et al, <sup>20</sup> 2003 <sup>e</sup>	B	PVS (Gore-Tex)	Burch	17	19	73 mo	X		X	X		
Enzelsberger et al, <sup>21</sup> 1996	C	PVS (dura mater)	Burch	36	36	36 mo	X		X	X		
PVS vs MUS												
Amaro et al, <sup>22</sup> 2009	C	PVS (autologous fascia)	Retropubic MUS (TVT)	21	20	44 mo		X	X	X	X	
Bai et al, <sup>9</sup> 2005 <sup>a</sup>	B	PVS (autologous fascia)	Retropubic MUS (TVT)	28	31	12 mo	X			X		
Guerrero et al, <sup>23</sup> 2010 <sup>f</sup>	B	PVS (autologous fascia)	Retropubic MUS (TVT)	79	50	12 mo		X	X	X	X	
Sharifiaghdas and Mortazavi, <sup>24</sup> 2008	B	PVS (autologous fascia)	Retropubic MUS (TVT)	52	48	40 mo	X	X	X	X	X	
Tcherniakovsky et al, <sup>25</sup> 2009	C	PVS (autologous fascia)	Obturator MUS (Safyre T)	20	21	12 mo	X		X	X		
Retropubic vs obturator MUS												
Aniulienė, <sup>26</sup> 2009	C	TVT	TVT-O	114	150	12 mo		X	X	X		
Araco et al, <sup>27</sup> 2008	B	TVT	TVT-O	108	100	12 mo	X		X	X	X	
Ballester et al, <sup>28</sup> 2012 <sup>g</sup>	B	Retropubic ISTOP	Transobturator ISTOP	42	46	48 mo	X	X	X	X	X	

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

(continued)

TABLE 1

## Randomized controlled trials included in systematic review (continued)

Study	Study quality <sup>r</sup>	Intervention	Comparator	n, intervention	n, comparator	Follow-up duration	OC	SC	Po	AE	QoL	SF
Barber et al, <sup>29</sup> 2008 <sup>h</sup>	A	TVT	Monarc	88	82	18 mo	X	X	X	X	X	X
Deffieux et al, <sup>30</sup> 2010	A	TVT	TVT-O	75	74	24 mo	X	X	X	X	X	X
El-Hefnawy et al, <sup>31</sup> 2010	C	TVT	Obturator MUS (unspecified)	19	21	20 mo	X	X	X	X		
Freeman et al, <sup>32</sup> 2011	A	TVT	Monarc	93	100	12 mo		X	X	X	X	X
Karateke et al, <sup>33</sup> 2009	A	TVT	TVT-O	83	84	14 mo	X	X	X	X	X	
Krofta et al, <sup>34</sup> 2010	A	TVT	TVT-O	149	151	12 mo	X	X	X	X	X	X
Liapis et al, <sup>35</sup> 2006	C	TVT	TVT-O	46	43	12 mo	X	X	X	X		
Richter et al, <sup>1</sup> 2010 (TOMUS Trial) <sup>i</sup>	A	TVT	Obturator MUS (TVT-O or Monarc)	298	299	24 mo	X	X	X	X	X	X
Rinne et al, <sup>36</sup> 2008 <sup>j</sup>	A	TVT	TVT-O	136	131	36 mo	X	X	X	X	X	
Ross et al, <sup>37</sup> 2009	B	Retropubic MUS (Advantage)	Obturator MUS (Obtryx)	105	94	12 mo	X	X	X	X	X	X
Scheiner et al, <sup>38</sup> 2012 <sup>k</sup>	B	TVT	Monarc	80	40	12 mo	X	X	X	X	X	X
Scheiner et al, <sup>38</sup> 2012 <sup>k</sup>	B	TVT	TVT-O	80	40	12 mo	X	X	X	X	X	X
Schierlitz et al, <sup>39</sup> 2008 <sup>l</sup>	B	TVT	Monarc	82	82	36 mo	X	X	X	X		X
Teo et al, <sup>40</sup> 2011	B	TVT	TVT-O	66	61	12 mo	X	X	X	X	X	
Wang F et al, <sup>41</sup> 2010	A	TVT	Obturator MUS (out-to-in)	70	70	12 mo	X	X	X	X	X	
Wang W et al, <sup>42</sup> 2009	B	TVT	TVT-O	160	155	36 mo	X		X	X		
Wang YJ et al, <sup>43</sup> 2011 <sup>m</sup>	B	TVT	TVT-O	32	36	12 mo	X		X	X		
Zullo et al, <sup>44</sup> 2007 <sup>n</sup>	B	TVT	TVT-O	35	37	5 y	X	X	X	X	X	X
Retropubic MUS vs retropubic MUS												
Andonian et al, <sup>45</sup> 2005	B	SPARC	TVT	41	43	12 mo	X	X	X	X		
Tseng et al, <sup>46</sup> 2005	B	SPARC	TVT	31	31	24 mo	X		X	X		
Obturator MUS vs obturator MUS												
Abdel-Fattah et al, <sup>47</sup> 2010 (E-TOT Trial) <sup>o</sup>	B	ARIS TOT (out-to-in)	TVT-O (in-to-out)	171	170	12 mo	X	X		X	X	X
Scheiner et al, <sup>38</sup> 2012 <sup>k</sup>	B	Monarc	TVT-O	40	40	12 mo	X	X	X	X	X	

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(continued)

TABLE 1

**Randomized controlled trials included in systematic review** (continued)

Study	Study quality <sup>r</sup>	Intervention	Comparator	n, intervention	n, comparator	Follow-up duration	OC	SC	Po	AE	QoL	SF
Minisling vs any other sling												
Andrada Hamer et al, <sup>48</sup> 2013	B	TVT-Secur H	TVT	64	69	12 mo	X	X	X	X		
Barber et al, <sup>49</sup> 2012	A	TVT-Secur U	TVT	136	127	12 mo	X	X	X	X	X	X
Hinoul et al, <sup>50</sup> 2011	A	TVT-Secur H	TVT-O	97	98	12 mo	X	X	X	X	X	
Hota et al, <sup>51</sup> 2012	A	TVT-O	TVT-Secur	44	42	12 mo	X	X	X	X	X	
Kim et al, <sup>52</sup> 2010	B	TVT-Secur U	TVT-Secur H	53	62	12 mo	X	X	X	X	X	X
Lee et al, <sup>53</sup> 2010	A	TVT-Secur U	TVT-Secur H	165	165	12 mo	X	X	X	X	X	X
Masata et al, <sup>54</sup> 2012 <sup>p</sup>	A	TVT-Secur U	TVT-O	65	68	24 mo	X	X	X	X	X	
Masata et al, <sup>54</sup> 2012 <sup>p</sup>	A	TVT-Secur H	TVT-O	64	68	24 mo	X	X	X	X	X	
Masata et al, <sup>54</sup> 2012 <sup>p</sup>	A	TVT-Secur U	TVT-Secur H	65	64	24 mo	X	X	X	X	X	
Oliveira et al, <sup>55</sup> 2011 <sup>q</sup>	C	TVT-Secur H	TVT-O	30	30	12 mo	X		X	X		
Oliveira et al, <sup>55</sup> 2011 <sup>q</sup>	C	MiniArc	TVT-O	30	30	12 mo	X		X	X		
Oliveira et al, <sup>55</sup> 2011 <sup>q</sup>	C	TVT-Secur H	MiniArc	30	30	12 mo	X		X	X		
Tommaselli et al, <sup>56</sup> 2010	B	TVT-Secur H	TVT-O	42	42	12 mo	X		X	X	X	
Wang YJ et al, <sup>43</sup> 2011 <sup>m</sup>	B	TVT-Secur	TVT	34	32	12 mo	X		X	X		
Wang YJ et al, <sup>43</sup> 2011 <sup>m</sup>	B	TVT-Secur	TVT-O	34	36	12 mo	X		X	X		

Advantage; Boston Scientific Corp., Natick, MA; Gore-Tex; Gore Medical, Flagstaff, AZ; ISTOP, CL Medical, Winchester, MA; MiniArc; AMS, Minnetonka, MN; Monarc; AMS; Obtryx; Boston Scientific Corp.; Safyre; Promedon, Cordoba, Argentina; SPARC; AMS; TVT-O; Ethicon Gynecare, Cincinnati, OH; TVT-Secur, Ethicon Gynecare.

AE, adverse event; MUS, midurethral sling; OC, objective cure; Po, perioperative outcomes; PVS, pubovaginal sling; QoL, Life-of-life outcomes; SC, subjective cure; SF, sexual function outcomes; TOMUS, Trial of Midurethral Slings; TVT, tension-free vaginal tape; TVT-O, tension-free vaginal tape obturator.

<sup>a</sup> 3-Arm trial comparing PVS (autologous fascia) vs TVT vs Burch; <sup>b</sup> Jelovsek et al<sup>59</sup> 2008; <sup>c</sup> Ward et al<sup>60</sup> 2004 and Ward et al<sup>61</sup> 2008; <sup>d</sup> Tennstedt et al<sup>62</sup> 2005, Tennstedt et al<sup>63</sup> 2008, Chai et al<sup>64</sup> 2009, Kraus et al<sup>65</sup> 2011, Brubaker et al<sup>66</sup> 2012; <sup>e</sup> Sand et al<sup>67</sup> 2000; <sup>f</sup> Trial also included PVS (Pelvicol) arm (n = 72) that was not included as Pelvicol is off market; <sup>g</sup> Darai et al<sup>68</sup> 2007 and David-Montefiore et al<sup>69</sup> 2006; <sup>h</sup> Barber et al<sup>70</sup> 2008; <sup>i</sup> Albo<sup>71</sup> 2008, Brubaker et al<sup>72</sup> 2011, Zyczynski et al<sup>73</sup> 2012, Albo et al<sup>74</sup> 2012; <sup>j</sup> Laurikainen et al<sup>75</sup> 2007 and Palva et al<sup>76</sup> 2010; <sup>k</sup> 3-Arm trial comparing Monarc vs TVT vs TVT-O; <sup>l</sup> Schierlitz et al<sup>76</sup> 2012 and De Souza et al<sup>77</sup> 2012; <sup>m</sup> 3-Arm trial comparing TVT-Secur vs TVT vs TVT-O; <sup>n</sup> Angioli et al<sup>78</sup> 2010; <sup>o</sup> Abdel-Fattah et al<sup>79</sup> 2010 and Abdel-Fattah et al<sup>80</sup> 2012; <sup>p</sup> 3-Arm trial comparing TVT-Secur H vs TVT-Secur U vs TVT-O; <sup>q</sup> 3-Arm trial comparing TVT-O vs TVT-Secur H vs MiniArc; <sup>r</sup> A (good), B (fair), C (poor).

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### Categorization of outcomes analyzed from randomized controlled trials

Outcome category of interest	Specific outcomes collected
Objective cure	Cough stress test
	Pad testing
	Urodynamic stress incontinence
	Voiding diary data
Subjective cure	Sandvik Incontinence Severity Index
	International Consultation on Incontinence Questionnaire (ICIQ)
	Patient Global Impression of Improvement (PGI-I)
	Pelvic Floor Distress Inventory (PFDI)
	Urinary Distress Inventory (UDI)
	Bristol female lower urinary tract symptom (BFLUTS)
	Measures such as “better” or “satisfied”
	“Would recommend to a friend”
	Met expectations
Perioperative outcomes	Estimated blood loss, time to return to normal activity/work, operative time, hospital time, length of stay, length of use of catheter, pain
Quality of life or satisfaction	Kings Health Questionnaire (KHQ)
	Measures of activities of daily living
	Urinary Incontinence Quality-of-life Scale (I-QOL)
	Bristol female lower urinary tract symptom (BFLUTS)
	Pelvic Floor Impact Questionnaire/Incontinence Impact Questionnaire (PFIQ/IIQ)
	International Consultation on Incontinence Questionnaire (ICIQ)
	CONTILIFE (Quality-of-life Assessment Questionnaire Concerning Urinary Incontinence)
Sexual function	Bristol female lower urinary tract symptom (BFLUTS)
	Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR)
	CONTILIFE (Quality-of-life Assessment Questionnaire Concerning Urinary Incontinence)
	Dyspareunia
	“Return to normal sex life”
Adverse events	Table 3

*IUGA*, International Urogynecology Association.

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surgery was not collected. Sling types of interest included MUS (retropubic, obturator), pubovaginal slings at the bladder neck (biologic, synthetic, or autologous), and minislings. All studies had to report results for cohorts (or study arms) of women who all received the same sling type (or Burch urethropexy); studies that combined women who received different sling types in their analyses were excluded. Studies that examined various aspects of surgical technique, anesthesia, or surgeon training were excluded if the same type of sling was used in each arm. Data were excluded if the surgical product used was not available in the United States as of April 2013.

Outcomes of interest from RCTs fell into 6 categories: objective cure, subjective cure, perioperative outcomes, quality of life or satisfaction, sexual function, and AEs (Table 2). Studies with non-randomized designs were included only for AEs. Information on cost was not collected.

## Data extraction and quality assessment

Data were extracted by 1 of 12 reviewers using a standard data extraction form and confirmed by another; discrepancies were resolved by consensus. We extracted data on study characteristics, participant characteristics, funding source, details on the interventions, length of follow-up, outcomes of interest measured, and how these outcomes were assessed. After data extraction, the lead reviewer and methodologist categorized all outcomes extracted from the RCTs into the 6 outcome categories listed above. Two reviewers also categorized all AEs into 22 categories as listed in Table 3. The underlying data, together with additional extracted information, are accessible online at <http://srdcr.ahrq.gov/> in the project Sling surgery for stress urinary incontinence in women: Society of Gynecologic Surgeons 2013.

We assessed the methodological quality of each RCT using predefined criteria from a 3-category system modified from the Agency for Healthcare Research and Quality.<sup>5</sup> Studies were graded as good (A), fair (B), or poor (C).

also included trials excluded from RCT analysis, nonrandomized comparative studies, and cohort (pre-post) studies of any follow-up duration. Because of the volume of these studies, sample size limitations were placed to restrict the

number of studies to only those with the most patients and therefore highest potential for identifying a complication (Figure 1). Studies included for AEs had to evaluate at least 1 sling type, and information about any other comparator

TABLE 3

Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies<sup>1,9-57,59-117</sup>

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Estimated blood loss >200 mL					
Obturator	4	0.22% (0.03–1.59%)	1	448	0.00–1.79%
Minisling	3	1.1% (0.5–1.9%)	10	888	0.00–3.68%
Retropubic	4	1.5% (1.0–2.1%)	33	2071	0.21–4.76%
Transfusion					
Burch	3	0.00% (0.00–7.73%)	0	105	0.00–0.00%
Obturator	6	0.17% (0.02–1.22%)	1	584	0.00–0.40%
Retropubic	13	0.40% (0.28–0.55%)	31	8105	0.00–4.00%
Minisling	5	0.51% (0.23–1.14%)	6	1177	0.00–0.74%
Pubovaginal	5	1.9% (0.9–3.2%)	10	515	0.00–5.17%
Hematoma					
Obturator	18	0.59% (0.35–0.89%)	17	2995	0.00–2.41%
Retropubic	25	0.88% (0.74–1.0%)	184	15,950	0.00–16.13%
Minisling	2	0.85% (0.21–3.44%)	2	236	0.74–1.00%
Burch	4	1.4% (0.6–2.6%)	8	542	0.00–5.71%
Pubovaginal	5	2.2% (1.2–3.4%)	14	677	0.00–5.17%
Dyspareunia					
Retropubic	2	0.00% (0.01–1.64%)	0	488	0.00–0.00%
Obturator	6	0.16% (0.02–1.14%)	1	624	0.00–0.40%
Minisling	11	0.74% (0.40–1.2%)	19	1809	0.00–6.49%
Pubovaginal	5	0.99% (0.39–1.9%)	8	696	0.00–2.63%
Return to operating room for erosion					
Burch	2	0.28% (0.04–2.03%)	1	352	0.00–0.30%
Minisling	3	1.4% (0.5–2.8%)	5	399	0.53–2.86%
Pubovaginal	5	1.6% (0.8–2.7%)	16	640	0.00–12.50%
Retropubic	12	1.9% (1.0–3.0%)	13	703	0.00–6.45%
Obturator	7	2.7% (1.5–4.3%)	14	518	0.00–8.24%
Exposure					
Burch	4	0.00% (0.02–6.22%)	0	130	0.00–0.00%
Retropubic	29	1.4% (1.1–1.7%)	84	5684	0.00–12.90%
Minisling	19	2.0% (1.5–2.6%)	61	2408	0.00–19.05%
Obturator	31	2.2% (1.7–2.7%)	66	3253	0.00–10.00%
Pubovaginal	10	5.4% (4.0–7.0%)	48	851	0.00–15.52%
Wound infection					
Minisling	3	0.31% (0.05–0.80%)	2	852	0.00–1.04%
Obturator	14	0.74% (0.43–1.1%)	14	2348	0.00–2.11%

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(continued)



**Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies**<sup>1,9-57,59-117</sup> (continued)

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Retropubic	13	0.75% (0.54–0.98%)	43	5781	0.00–13.04%
Pubovaginal	3	2.6% (0.8–5.4%)	4	174	0.85–5.56%
Burch	5	7.0% (4.3–10%)	17	269	3.13–9.68%
Urinary tract infection					
Minisling	13	3.6% (2.8–4.6%)	72	1762	0.74–18.33%
Pubovaginal	4	4.2% (2.5–6.3%)	21	420	1.84–18.75%
Obturator	21	4.3% (3.4–5.2%)	88	1826	0.00–16.79%
Burch	7	5.9% (4.2–7.9%)	55	648	0.00–31.51%
Retropubic	21	11.0% (9.7–11%)	718	6286	0.00–23.33%
Bowel injury					
Obturator	5	0.00% (0.00–1.96%)	0	410	0.00–0.00%
Retropubic	7	0.34% (0.09–1.36%)	2	594	0.00–1.57%
Minisling	1	0.74% (0.10–5.30%)	1	136	0.74–0.74%
Burch	1	3.13% (0.44–23.63%)	1	32	3.13–3.13%
Nerve injury					
Minisling	1	0.00% (0.02–5.95%)	0	136	0.00–0.00%
Retropubic	4	0.06% (0.01–0.43%)	1	1642	0.00–0.07%
Obturator	3	0.61% (0.09–4.36%)	1	165	0.00–1.72%
Ureteral injury					
Retropubic	1	0.00% (0.00–9.25%)	0	88	0.00–0.00%
Pubovaginal	4	0.18% (0.03–1.26%)	1	567	0.00–1.28%
Burch	1	0.61% (0.15–2.46%)	2	329	0.61–0.61%
Obturator	1	1.22% (0.17–8.87%)	1	82	1.22–1.22%
Vascular injury					
Obturator	2	0.00% (0.00–6.75%)	0	120	0.00–0.00%
Retropubic	4	0.08% (0.04–0.18%)	6	7149	0.00–0.09%
Overactive bladder/urgency					
Burch	3	4.3% (2.5–6.5%)	17	387	2.86–21.74%
Obturator	8	5.3% (4.2–6.5%)	106	1485	0.00–34.53%
Minisling	11	5.4% (4.4–6.5%)	103	1769	2.22–21.00%
Retropubic	15	6.9% (6.0–7.7%)	374	3486	0.76–45.00%
Pubovaginal	5	8.6% (6.5–11%)	55	558	3.37–38.10%
Retention lasting <6 wk postoperatively					
Minisling	13	2.1% (1.5–2.8%)	36	1778	0.00–5.88%
Obturator	17	2.3% (1.8–3.0%)	70	2629	0.00–10.00%
Retropubic	18	3.1% (2.7–3.5%)	248	7127	0.00–21.74%

(continued)

TABLE 3

Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies<sup>1,9-57,59-117</sup> (continued)

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Pubovaginal	10	12% (10.2–14%)	158	1053	3.03–81.97%
Burch	5	17% (13–21%)	55	288	0.00–32.88%
Retention lasting >6 wk postoperatively					
Obturator	6	2.4% (1.4–3.6%)	70	2629	0.00–10.00%
Retropubic	9	2.7% (2.1–3.4%)	248	7127	0.00–21.74%
Minisling	2	3.3% (1.6–5.7%)	36	1778	0.00–5.88%
Pubovaginal	6	7.5% (5.4–10%)	158	1053	3.03–81.97%
Burch	4	7.6% (4.7–11%)	55	288	0.00–32.88%
Return to operating room for urinary retention					
Burch	4	0.00% (0.00–1.54%)	0	522	0.00–0.00%
Obturator	22	1.1% (0.7–1.5%)	23	2342	0.00–6.67%
Retropubic	21	1.2% (0.9–1.7%)	48	3103	0.00–24.00%
Minisling	12	1.9% (1.2–2.9%)	16	970	0.00–5.00%
Pubovaginal	15	3.0% (2.3–3.9%)	57	1667	0.00–7.69%
Groin pain					
Pubovaginal	2	0.34% (0.09–1.36%)	2	591	0.00–0.61%
Minisling	12	0.62% (0.30–1.1%)	14	1619	0.00–5.26%
Burch	2	1.10% (0.42–2.98%)	4	364	0.00–11.43%
Retropubic	12	1.5% (1.0–2.1%)	29	1811	0.00–5.56%
Obturator	17	6.5% (5.3–7.7%)	128	1594	0.00–36.67%
Leg pain					
Retropubic	4	0.62% (0.16–2.51%)	2	322	0.00–1.69%
Minisling	4	1.6% (0.5–3.2%)	4	337	0.00–2.63%
Obturator	7	16% (13–19%)	112	649	3.66–60.87%
Bladder perforation					
Obturator	32	0.70% (0.46–0.98%)	22	4000	0.00–4.76%
Minisling	6	0.85% (0.40–1.5%)	12	1138	0.00–4.41%
Pubovaginal	14	2.3% (1.5–3.3%)	23	1069	0.00–5.56%
Burch	10	2.8% (1.7–4.1%)	19	753	0.00–6.25%
Retropubic	41	3.6% (3.3–3.9%)	420	11,390	0.00–24.39%
Urethral perforation					
Burch	1	0.00% (0.00–34.04%)	0	25	0.00–0.00%
Obturator	7	0.20% (0.05–0.80%)	2	1013	0.00–1.72%
Retropubic	8	0.41% (0.19–0.72%)	17	2211	0.00–5.37%
Minisling	1	2.70% (0.38–20.26%)	1	37	2.70–2.70%

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